

Calendar No. 118

104TH CONGRESS
1ST SESSION

S. 343

[Report No. 104-89]
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A BILL

To reform the regulatory process, and for other purposes.

May 26 (legislative day, May 15), 1995
Reported with an amendment in the nature of a
substitute

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To reform the regulatory process, and for other purposes.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 2 (legislative day, JANUARY 30), 1995

Mr. DOLE (for himself, Mr. NICKLES, Mr. BOND, Mrs. HUTCHISON, Mr. MURKOWSKI, Mr. LOTT, Mr. COCHRAN, Mr. HATCH, Mr. DOMENICI, Mrs. KASSEBAUM, Mr. COATS, Mr. ABRAHAM, Mr. INHOFE, Mr. SMITH, Mr. SANTORUM, Mr. THOMPSON, Mr. WARNER, Mr. KYL, Mr. THOMAS, Mr. GRAMM, Mr. MACK, Mr. GREGG, Mr. SHELBY, Mr. STEVENS, Mr. HELMS, Mr. FAIRCLOTH, Mr. GRASSLEY, Mr. KEMPTHORNE, Mr. SIMPSON, and Mr. FRIST) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

FEBRUARY 3 (legislative day, JANUARY 30), 1995

Ordered referred jointly to the Committees on the Judiciary and Governmental Affairs

MAY 26 (legislative day, MAY 15), 1995

Reported by Mr. ROTH, from the Committee on Governmental Affairs, with an amendment in the nature of a substitute

[Strike out all after the enacting clause and insert the part printed in italic]

MAY 26 (legislative day, MAY 15), 1995

And on behalf of Mr. HATCH, from the Committee on the Judiciary, with an amendment in the nature of a substitute

[Omit the part enclosed in bold brackets and insert the part printed in bold italic]

A BILL

To reform the regulatory process, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Comprehensive Regu-
5 latory Reform Act of 1995”.

6 **SEC. 2. ANALYSIS OF AGENCY PROPOSALS.**

7 ~~(a) IN GENERAL.~~—Chapter 6 of title 5, United
8 States Code, is amended by adding at the end the follow-
9 ing:

10 “SUBCHAPTER II—ANALYSIS OF AGENCY
11 PROPOSALS

12 **“§ 621. Definitions**

13 “For purposes of this subchapter and subchapter III
14 of this chapter—

15 “(1) the term ‘agency’ has the same meaning as
16 in section 551(1) of this title;

17 “(2) the term ‘person’ has the same meaning as
18 in section 551(2) of this title;

19 “(3) the term ‘rule’ has the same meaning as
20 in section 551(4) of this title;

21 “(4)(A) the term ‘major rule’ means—

22 “(i) a rule or a group of closely related
23 rules that the agency proposing the rule or the

1 President reasonably determines is likely to
 2 have a gross annual effect on the economy of
 3 \$50,000,000 or more in reasonably quantifiable
 4 increased direct and indirect costs; or has a sig-
 5 nificant impact on a sector of the economy; or
 6 “(ii) a rule or a group of closely related
 7 rules that is otherwise designated a major rule
 8 by the agency proposing the rule, or by the
 9 President on the ground that the rule is likely
 10 to result in—

11 “(I) a substantial increase in costs or
 12 prices for wage earners, consumers, indi-
 13 vidual industries, nonprofit organizations,
 14 Federal, State, or local government agen-
 15 cies; or geographic regions; or

16 “(II) significant adverse effects on
 17 competition, employment, investment, pro-
 18 ductivity, innovation, the environment,
 19 public health or safety, or the ability of en-
 20 terprises whose principal places of business
 21 are in the United States to compete in do-
 22 mestic or export markets;

23 “(B) the term ‘major rule’ does not include—

24 “(i) a rule that involves the internal reve-
 25 nue laws of the United States; or

1 “(ii) a rule that authorizes the introduction
2 into commerce, or recognizes the marketable
3 status, of a product;

4 “(5) the term ‘benefit’ means the reasonably
5 identifiable significant benefits, including social and
6 economic benefits, that are expected to result di-
7 rectly or indirectly from implementation of a rule or
8 an alternative to a rule;

9 “(6) the term ‘cost’ means the reasonably iden-
10 tifiable significant costs and adverse effects, includ-
11 ing social and economic costs, reduced consumer
12 choice, substitution effects, and impeded techno-
13 logical advancement, that are expected to result di-
14 rectly or indirectly from implementation of, or com-
15 pliance with, a rule or an alternative to a rule; and

16 “(7) the term ‘market-based mechanism’ means
17 a regulatory program that—

18 “(A) imposes legal accountability for the
19 achievement of an explicit regulatory objective
20 on each regulated person;

21 “(B) affords maximum flexibility to each
22 regulated person in complying with mandatory
23 regulatory objectives, which flexibility shall,
24 where feasible and appropriate, include, but not
25 be limited to, the opportunity to transfer to, or

1 receive from, other persons, including for cash
 2 or other legal consideration, increments of com-
 3 pliance responsibility established by the pro-
 4 gram; and

5 “(C) permits regulated persons to respond
 6 automatically to changes in general economic
 7 conditions and in economic circumstances di-
 8 rectly pertinent to the regulatory program with-
 9 out affecting the achievement of the program’s
 10 explicit regulatory mandates.

11 **“§ 622. Rulemaking cost-benefit analysis**

12 “(a)(1) Prior to publishing notice of a proposed rule-
 13 making for any rule (or, in the case of a notice of a pro-
 14 posed rulemaking that has been published on or before the
 15 date of enactment of this subchapter, not later than 30
 16 days after such date of enactment), each agency shall de-
 17 termine whether the rule is or is not a major rule within
 18 the meaning of section 621(4)(A)(i) and, if it is not,
 19 whether it should be designated a major rule under section
 20 621(4)(A)(ii). For the purpose of any such determination
 21 or designation, a group of closely related rules shall be
 22 considered as one rule.

23 “(2) Each notice of proposed rulemaking shall in-
 24 clude a succinct statement and explanation of the agency’s
 25 determination under paragraph (1).

1 ~~“(b)(1) If an agency has determined that a rule is~~
2 ~~not a major rule within the meaning of section~~
3 ~~621(4)(A)(i) and has not designated the rule a major rule~~
4 ~~within the meaning of section 621(4)(A)(ii), the President~~
5 ~~may, as appropriate, determine that the rule is a major~~
6 ~~rule or designate the rule a major rule not later than 30~~
7 ~~days after the publication of the notice of proposed rule-~~
8 ~~making for the rule (or, in the case of a notice of proposed~~
9 ~~rulemaking that has been published on or before the date~~
10 ~~of enactment of this subchapter, not later than 60 days~~
11 ~~after such date of enactment).~~

12 ~~“(2) Such determination or designation shall be pub-~~
13 ~~lished in the Federal Register, together with a succinct~~
14 ~~statement of the basis for the determination or designa-~~
15 ~~tion.~~

16 ~~“(c)(1)(A) When the agency publishes a notice of pro-~~
17 ~~posed rulemaking for a major rule, the agency shall issue~~
18 ~~and place in the rulemaking record a draft cost-benefit~~
19 ~~analysis, and shall include a summary of such analysis in~~
20 ~~the notice of proposed rulemaking.~~

21 ~~“(B)(i) When the President has published a deter-~~
22 ~~mination or designation that a rule is a major rule after~~
23 ~~the publication of the notice of proposed rulemaking for~~
24 ~~the rule, the agency shall promptly issue and place in the~~
25 ~~rulemaking file a draft cost-benefit analysis for the rule~~

1 and shall publish in the Federal Register a summary of
2 such analysis.

3 ~~“(ii) Following the issuance of a draft cost-benefit~~
4 ~~analysis under clause (i), the agency shall give interested~~
5 ~~persons an opportunity to comment pursuant to section~~
6 ~~553 of this title in the same manner as if the draft cost-~~
7 ~~benefit analysis had been issued with the notice of pro-~~
8 ~~posed rulemaking.~~

9 ~~“(2) Each draft cost-benefit analysis shall contain—~~

10 ~~“(A) an analysis of the benefit of the proposed~~
11 ~~rule; and an explanation of how the agency antici-~~
12 ~~pates each benefit will be achieved by the proposed~~
13 ~~rule;~~

14 ~~“(B) an analysis of the costs of the proposed~~
15 ~~rule; and an explanation of how the agency antici-~~
16 ~~pates each such cost will result from the proposed~~
17 ~~rule;~~

18 ~~“(C) an identification (including an analysis of~~
19 ~~the costs and benefits) of reasonable alternatives for~~
20 ~~achieving the identified benefits of the proposed rule,~~
21 ~~including alternatives that—~~

22 ~~“(i) require no Government action;~~

23 ~~“(ii) will accommodate differences among~~
24 ~~geographic regions and among persons with dif-~~

1 fering levels of resources with which to comply;
2 and

3 ~~“(iii) employ performance or other market-~~
4 ~~based standards that permit the greatest flexi-~~
5 ~~bility in achieving the identified benefits of the~~
6 ~~proposed rule and that comply with the require-~~
7 ~~ments of subparagraph (D);~~

8 ~~“(D) an assessment of the feasibility of estab-~~
9 ~~lishing a regulatory program that operates through~~
10 ~~the application of market-based mechanisms;~~

11 ~~“(E) in any case in which the proposed rule is~~
12 ~~based on one or more scientific evaluations or infor-~~
13 ~~mation or is subject to the risk assessment require-~~
14 ~~ments of subchapter III, a description of actions un-~~
15 ~~dertaken by the agency to verify the quality, reliabil-~~
16 ~~ity, and relevance of such scientific evaluations or~~
17 ~~scientific information in accordance with the risk as-~~
18 ~~essment requirements of subchapter III;~~

19 ~~“(F) an assessment of the aggregate effect of~~
20 ~~the rule on small businesses with fewer than 100~~
21 ~~employees, including an assessment of the net em-~~
22 ~~ployment effect of the rule; and~~

23 ~~“(G) an analysis of whether the identified bene-~~
24 ~~fits of the proposed rule are likely to exceed the~~
25 ~~identified costs of the proposed rule, and an analysis~~

1 of whether the proposed rule will provide greater net
2 benefits to society than any of the alternatives to the
3 proposed rule, including alternatives identified in ac-
4 cordance with subparagraph (C).

5 “(d)(1) When the agency publishes a final major rule,
6 the agency shall also issue and place in the rulemaking
7 record a final cost-benefit analysis, and shall include a
8 summary of the analysis in the statement of basis and
9 purpose.

10 “(2) Each final cost-benefit analysis shall contain—

11 “(A) a description and comparison of the bene-
12 fits and costs of the rule and of the reasonable alter-
13 natives to the rule described in the rulemaking, in-
14 cluding the market-based mechanisms identified pur-
15 suant to subsection (c)(2)(D); and

16 “(B) an analysis, based upon the rulemaking
17 record considered as a whole, of—

18 “(i) whether the benefits of the rule out-
19 weigh the costs of the rule; and

20 “(ii) whether the rule will provide greater
21 net benefits to society than any of the alter-
22 natives described in the rulemaking, including
23 the market-based incentives identified pursuant
24 to subsection (c)(2)(D).

1 ~~“(c)(1)(A) The description of the benefits and costs~~
2 ~~of a proposed and a final rule required under this section~~
3 ~~shall include, to the extent feasible, a quantification or nu-~~
4 ~~merical estimate of the quantifiable benefits and costs.~~
5 ~~Such quantification or numerical estimate shall be made~~
6 ~~in the most appropriate unit of measurement, using com-~~
7 ~~parable assumptions, including time periods, and shall~~
8 ~~specify the ranges of predictions and shall explain the~~
9 ~~margins of error involved in the quantification methods~~
10 ~~and in the estimates used. An agency shall describe the~~
11 ~~nature and extent of the nonquantifiable benefits and~~
12 ~~costs of a final rule pursuant to this section in as precise~~
13 ~~and succinct a manner as possible.~~

14 ~~“(B) Where practicable, the description of the bene-~~
15 ~~fits and costs of a proposed and final rule required under~~
16 ~~this section shall describe such benefits and costs on an~~
17 ~~industry by industry basis.~~

18 ~~“(2)(A) In evaluating and comparing costs and bene-~~
19 ~~fits and in evaluating the risk assessment information de-~~
20 ~~veloped pursuant to subchapter III, the agency shall not~~
21 ~~rely on cost, benefit, or risk assessment information that~~
22 ~~is not accompanied by data, analysis, or other supporting~~
23 ~~materials that would enable the agency and other persons~~
24 ~~interested in the rulemaking to assess the accuracy, reli-~~

1 ability, and uncertainty factors applicable to such informa-
 2 tion.

3 “(B) The agency evaluations of the relationships of
 4 the benefits of a proposed and final rule to its costs shall
 5 be clearly articulated in accordance with this section.

6 **“§ 623. Decisional criteria**

7 “(a) No final rule subject to this subchapter shall be
 8 promulgated unless the agency finds that—

9 “(1) the potential benefits to society from the
 10 rule outweigh the potential costs of the rule to soci-
 11 ety, as determined by the analysis required by sec-
 12 tion 622(d)(2)(B); and

13 “(2) the rule will provide greater net benefits to
 14 society than any of the reasonable alternatives iden-
 15 tified pursuant to section 622(c)(2)(C), including the
 16 market-based mechanisms identified pursuant to sec-
 17 tion 622(c)(2)(D).

18 “(b) The requirements of this section shall supple-
 19 ment the decisional criteria for rulemaking otherwise ap-
 20 plicable under the statute granting the rulemaking author-
 21 ity, except when such statute contains explicit textual lan-
 22 guage prohibiting the consideration of the criteria set
 23 forth in this section. Where the agency finds that consider-
 24 ation of the criteria set forth in this section is prohibited
 25 by explicit statutory language, the agency shall transmit

1 its finding to Congress, along with the final cost-benefit
 2 analysis required by section 622(d)(2)(B).

3 **~~“§ 624. Judicial review~~**

4 ~~“(a) Compliance or noncompliance by an agency with~~
 5 ~~the provisions of this subchapter shall be subject to judi-~~
 6 ~~cial review in accordance with this section.~~

7 ~~“(b)(1) Each of the following shall be subject to judi-~~
 8 ~~cial review:~~

9 ~~“(A) A determination by an agency or by the~~
 10 ~~President that a rule is or is not a major rule within~~
 11 ~~the meaning of section 621(4).~~

12 ~~“(B) A designation by an agency or by the~~
 13 ~~President of a rule as a major rule.~~

14 ~~“(C) A decision by an agency or by the Presi-~~
 15 ~~dent not to designate a rule a major rule.~~

16 ~~“(2) A determination by an agency or by the Presi-~~
 17 ~~dent that a rule is not a major rule within the meaning~~
 18 ~~of section 621(4), or the decision by an agency or by the~~
 19 ~~President not to designate a rule a major rule, shall be~~
 20 ~~set aside by a reviewing court only upon a showing of clear~~
 21 ~~and convincing evidence that the determination or decision~~
 22 ~~not to designate is erroneous in light of the information~~
 23 ~~available to the agency at the time the determination or~~
 24 ~~decision not to designate was made.~~

1 ~~“(3) An action to review a determination that a rule~~
 2 ~~is not a major rule or to review a decision not to designate~~
 3 ~~shall be filed not later than 30 days after the date of publi-~~
 4 ~~cation of such determination or failure to designate.~~

5 ~~“(c) If a court of the United States finds that a rule~~
 6 ~~should have been reviewed pursuant to this subchapter,~~
 7 ~~such rule shall have no force or effect until such time as~~
 8 ~~the requirements of this subchapter are met.~~

9 ~~“(d) Each court with jurisdiction to review final agen-~~
 10 ~~cy action under the statute granting the agency authority~~
 11 ~~to conduct the rulemaking shall have jurisdiction to review~~
 12 ~~findings by any agency under this subchapter and shall~~
 13 ~~set aside agency action that fails to satisfy the decisional~~
 14 ~~criteria of section 623. The court shall apply the same~~
 15 ~~standards of judicial review that apply to the review of~~
 16 ~~agency findings under the statute granting the agency au-~~
 17 ~~thority to conduct the rulemaking.~~

18 ~~“§ 625. Petition for cost-benefit analysis~~

19 ~~“(a)(1) Any person subject to a major rule may peti-~~
 20 ~~tion the relevant agency or the President to perform a~~
 21 ~~cost-benefit analysis under this subchapter for the major~~
 22 ~~rule, including a major rule in effect on the date of enact-~~
 23 ~~ment of this subchapter for which a cost-benefit analysis~~
 24 ~~pursuant to such subchapter has not been performed, re-~~
 25 ~~gardless of whether a cost-benefit analysis was previously~~

1 performed to meet requirements imposed before the date
2 of enactment of this subchapter.

3 ~~“(2) The petition shall identify with reasonable speci-~~
4 ~~ficity the major rule to be reviewed.~~

5 ~~“(3) The agency or the President shall grant the peti-~~
6 ~~tion if the petition shows that there is a reasonable likeli-~~
7 ~~hood that the costs of the major rule outweigh the bene-~~
8 ~~fits, or that reasonable questions exist as to whether the~~
9 ~~rule provides greater net benefits to society than any rea-~~
10 ~~sonable alternative to the rule that may be more clearly~~
11 ~~resolved through examination pursuant to this subchapter~~
12 ~~and subchapter III.~~

13 ~~“(4) A decision to grant or deny a petition under this~~
14 ~~subsection shall be made not later than 180 days after~~
15 ~~submittal. A decision to deny a petition shall be subject~~
16 ~~to judicial review immediately upon denial as final agency~~
17 ~~action under the statute granting the agency authority to~~
18 ~~conduct the rulemaking.~~

19 ~~“(b) For each major rule for which a petition has~~
20 ~~been granted under subsection (a), the agency shall con-~~
21 ~~duct a cost-benefit analysis in accordance with this sub-~~
22 ~~chapter, and shall determine whether the rule satisfies the~~
23 ~~decisional criteria set forth in section 623. If the rule does~~
24 ~~not satisfy the decisional criteria, then the agency shall~~
25 ~~take immediate action to either revoke or amend the rule~~

1 to conform the rule to the requirements of this subchapter
2 and the decisional criteria under section 623.

3 “(c) For purposes of this section, the term ‘major
4 rule’ means any major rule or portion thereof.

5 “(d)(1) Any person may petition the relevant agency
6 to withdraw, as contrary to this subchapter, any agency
7 guidance or general statement of policy that would be a
8 major rule if the guidance or general statement of policy
9 had been adopted as a rule.

10 “(2) The petition shall identify with reasonable speci-
11 ficity why the guidance or general statement of policy
12 would be major if adopted as a rule.

13 “(3) The agency shall grant the petition if the peti-
14 tion shows that there is a reasonable likelihood that the
15 guidance or general statement of policy would be major
16 if adopted as a rule.

17 “(4) A decision to grant or deny a petition under this
18 subsection shall be made not later than 180 days after
19 the petition is submitted. If the agency fails to act by such
20 date, the petition shall be deemed to have been granted.
21 A decision to deny a petition shall be subject to judicial
22 review immediately upon denial as final agency action
23 under the statute under which the agency has issued the
24 guidance or general statement of policy.

1 “(e) For each petition granted under subsection (d),
2 the agency shall be prohibited from enforcing against any
3 person the regulatory standards or criteria contained in
4 such guidance or policy unless included in a rule proposed
5 and promulgated in accordance with this subchapter.

6 **“§ 626. Effective date of final regulations**

7 “(a)(1) Beginning on the date of enactment of this
8 section, all deadlines in statutes that require agencies to
9 propose or promulgate any rule subject to this subchapter
10 are suspended until such time as the requirements of this
11 subchapter are satisfied.

12 “(2) Beginning on the date of enactment of this sec-
13 tion, the jurisdiction of any court of the United States
14 to enforce any deadline that would require an agency to
15 propose or promulgate a rule subject to subchapter II of
16 chapter 5 of title 5, United States Code (as added by this
17 section), is suspended until such time as the requirements
18 of this subchapter are satisfied.

19 “(3) In any case in which the failure to promulgate
20 a rule by a deadline would create an obligation to regulate
21 through individual adjudications, the obligation to conduct
22 individual adjudications shall be suspended to allow the
23 requirements of this subchapter to be satisfied.

24 “(b)(1) Before a major rule takes effect as a final
25 rule, the agency promulgating such rule shall submit to

1 the Congress a copy of such rule and a report containing
2 a concise general statement relating to the rule, including
3 a complete copy of the cost-benefit analysis, and the pro-
4 posed effective date of the rule.

5 “(2) A major rule relating to a report submitted
6 under paragraph (1) shall take effect as a final rule, the
7 latest of—

8 “(A) the later of the date occurring 45 days
9 after the date on which—

10 “(i) the Congress receives the report sub-
11 mitted under paragraph (1); or

12 “(ii) the rule is published in the Federal
13 Register;

14 “(B) if the Congress passes a joint resolution of
15 disapproval described under subsection (h) relating
16 to the rule, and the President signs a veto of such
17 resolution, the earlier date—

18 “(i) on which either House of Congress
19 votes and fails to override the veto of the Presi-
20 dent; or

21 “(ii) occurring 30 session days after the
22 date on which the Congress received the veto
23 and objections of the President; or

24 “(C) the date the rule would have otherwise
25 taken effect, if not for this section (unless a joint

1 resolution of disapproval under subsection (h) is en-
 2 acted).

3 “(c) A rule shall not take effect as a final rule if the
 4 Congress passes a joint resolution of disapproval described
 5 under subsection (h).

6 “(d)(1) Notwithstanding any other provision of this
 7 section (except subject to paragraph (3)), a rule that
 8 would not take effect by reason of this section may take
 9 effect if the President makes a determination under para-
 10 graph (2) and submits written notice of such determina-
 11 tion to the Congress.

12 “(2) Paragraph (1) applies to a determination made
 13 by the President by Executive order that the rule should
 14 take effect because such rule is—

15 “(A) necessary because of an imminent threat
 16 to health or safety or other emergency;

17 “(B) necessary for the enforcement of criminal
 18 laws; or

19 “(C) necessary for national security.

20 “(3) An exercise by the President of the authority
 21 under this subsection shall have no effect on the proce-
 22 dures under subsection (h) or the effect of a joint resolu-
 23 tion of disapproval under this section.

1 “(4) This subsection and an Executive order issued
2 by the President under this subsection shall not be subject
3 to judicial review by a court of the United States.

4 “(e)(1) Subsection (h) shall apply to any rule that
5 is published in the Federal Register (as a rule that shall
6 take effect as a final rule) during the period beginning
7 on the date occurring 60 days before the date the Con-
8 gress adjourns sine die through the date on which the suc-
9 ceeding Congress first convenes.

10 “(2) For purposes of subsection (h), a rule described
11 under paragraph (1) shall be treated as though such rule
12 were published in the Federal Register (as a rule that shall
13 take effect as a final rule) on the date the succeeding Con-
14 gress first convenes.

15 “(3) During the period between the date the Congress
16 adjourns sine die through the date on which the succeed-
17 ing Congress first convenes, a rule described under para-
18 graph (1) shall take effect as a final rule as otherwise pro-
19 vided by law.

20 “(f) Any rule that takes effect and later is made of
21 no force or effect by the enactment of a joint resolution
22 under subsection (h) shall be treated as though such rule
23 had never taken effect.

24 “(g) If the Congress does not enact a joint resolution
25 of disapproval under subsection (h), no court or agency

1 may infer any intent of the Congress from any action or
 2 inaction of the Congress with regard to such rule, related
 3 statute, or joint resolution of disapproval.

4 “(h)(1) For purposes of this subsection, the term
 5 ‘joint resolution’ means only a joint resolution introduced
 6 after the date on which the report referred to in subsection
 7 (b) is received by Congress the matter after the resolving
 8 clause of which is as follows: ‘That Congress disapproves
 9 the rule submitted by the ~~XXXX~~ relating to ~~XXXX~~, and
 10 such rule shall have no force or effect. (The blank spaces
 11 being appropriately filled in.)’.

12 “(2)(A) A resolution described in paragraph (1) shall
 13 be referred to the committees in each House of Congress
 14 with jurisdiction. Such a resolution shall not be reported
 15 before the eighth day after its submission or publication
 16 date.

17 “(B) For purposes of this subsection the term ‘sub-
 18 mission or publication date’ means the later of the date
 19 on which—

20 “(i) the Congress receives the report submitted
 21 under subsection (b)(1); or

22 “(ii) the rule is published in the Federal Reg-
 23 ister.

24 “(3) If the committee to which a resolution described
 25 in paragraph (1) is referred has not reported such resolu-

1 tion (or an identical resolution) at the end of 20 calendar
2 days after its submission or publication date; such com-
3 mittee may be discharged by the Majority Leader of the
4 Senate or the Majority Leader of the House of Represent-
5 atives, as the case may be, from further consideration of
6 such resolution and such resolution shall be placed on the
7 appropriate calendar of the House involved.

8 “(4)(A) When the committee to which a resolution
9 is referred has reported, or when a committee is dis-
10 charged (under paragraph (3)) from further consideration
11 of, a resolution described in paragraph (1), it shall at any
12 time thereafter be in order (even though a previous motion
13 to the same effect has been disagreed to) for any Member
14 of the respective House to move to proceed to the consider-
15 ation of the resolution, and all points of order against the
16 resolution (and against consideration of the resolution)
17 shall be waived. The motion shall be highly privileged in
18 the House of Representatives and shall be privileged in
19 the Senate and shall not be debatable. The motion shall
20 not subject to amendment, or to a motion to postpone,
21 or to a motion to proceed to the consideration of other
22 business. A motion to reconsider the vote by which the
23 motion is agreed to or disagreed to shall not be in order.
24 If a motion to proceed to the consideration of the resolu-

1 tion is agreed to, the resolution shall remain the unfin-
2 ished business of the respective House until disposed of.

3 ~~“(B) Debate on the resolution, and on all debatable~~
4 ~~motions and appeals in connection therewith, shall be lim-~~
5 ~~ited to not more than 10 hours, which shall be divided~~
6 ~~equally between those favoring and those opposing the res-~~
7 ~~olution. A motion further to limit debate shall be in order~~
8 ~~and shall not be debatable. An amendment to, or a motion~~
9 ~~to postpone, or a motion to proceed to the consideration~~
10 ~~of other business, or a motion to recommit the resolution~~
11 ~~shall not be in order. A motion to reconsider the vote by~~
12 ~~which the resolution is agreed to or disagreed to shall not~~
13 ~~be in order.~~

14 ~~“(C) Immediately following the conclusion of the de-~~
15 ~~bate on a resolution described in paragraph (1), and a sin-~~
16 ~~gle quorum call at the conclusion of the debate if re-~~
17 ~~quested in accordance with the rules of the appropriate~~
18 ~~House, the vote on final passage of the resolution shall~~
19 ~~occur.~~

20 ~~“(D) Appeals from the decisions of the Chair relating~~
21 ~~to the application of the rules of the Senate or the House~~
22 ~~of Representatives, as the case may be, to the procedure~~
23 ~~relating to a resolution described in paragraph (1) shall~~
24 ~~be decided without debate.~~

1 “(5) If, before the passage by one House of a resolu-
 2 tion of that House described in paragraph (1), that House
 3 receives from the other House a resolution described in
 4 paragraph (1), then the following procedures shall apply:

5 “(A) The resolution of the other House shall
 6 not be referred to a committee.

7 “(B) With respect to a resolution described in
 8 paragraph (1) of the House receiving the resolu-
 9 tion—

10 “(i) the procedure in that House shall be
 11 the same as if no resolution had been received
 12 from the other House; but

13 “(ii) the vote on final passage shall be on
 14 the resolution of the other House.

15 “(6) This subsection is enacted by Congress—

16 “(A) as an exercise of the rulemaking power of
 17 the Senate and House of Representatives, respec-
 18 tively, and as such it is deemed to be a part of the
 19 rules of each House, respectively, but applicable only
 20 with respect to the procedure to be followed in that
 21 House in the case of a resolution described in para-
 22 graph (1), and it supersedes other rules only to the
 23 extent that it is inconsistent with such rules; and

24 “(B) with full recognition of the constitutional
 25 right of either House to change the rules (so far as

1 relating to the procedure of that House) at any time,
2 in the same manner, and to the same extent as in
3 the case of any other rule of that House.

4 **“§ 627. Unauthorized rulemakings**

5 “(a) Notwithstanding any other provision of law, be-
6 ginning on July 1, 1995, any rule that expands Federal
7 power or jurisdiction beyond the level of regulatory action
8 needed to satisfy statutory requirements shall be prohib-
9 ited.

10 “(b) Nothing in this section shall be construed to pre-
11 vent any agency from promulgating a rule that repeals,
12 narrows, or streamlines a rule, regulation, or administra-
13 tive process, or from issuing or promulgating a rule pro-
14 viding for tax relief or clarification or reducing regulatory
15 burdens.

16 **“§ 628. Standard for review of agency interpretations**
17 **of an enabling statute**

18 “(a) In reviewing a final agency action under section
19 706 of this title, or under a statute that provides for re-
20 view of a final agency action, the reviewing court shall af-
21 firm the agency’s interpretation of the statute granting
22 authority to promulgate the rule if, applying traditional
23 principles of statutory construction, the reviewing court
24 finds that the interpretation is clearly the interpretation
25 of the statute intended by Congress.

1 “(b) If the reviewing court, applying traditional prin-
 2 ciples of statutory construction, finds that an interpreta-
 3 tion other than the interpretation applied by the agency
 4 is clearly the interpretation of the statute intended by
 5 Congress, the reviewing court shall find that the agency’s
 6 interpretation is erroneous and contrary to law.

7 “(c)(1) If the reviewing court, applying established
 8 principles of statutory construction, finds that the statute
 9 gives the agency discretion to choose from among a range
 10 of permissible statutory constructions, the reviewing court
 11 shall affirm the agency’s interpretation where the record
 12 on review establishes that—

13 “(A) the agency has correctly identified the
 14 range of permissible statutory constructions;

15 “(B) the interpretation chosen is one that is
 16 within that range; and

17 “(C) the agency has engaged in reasoned deci-
 18 sionmaking in determining that the interpretation,
 19 rather than other permissible constructions of the
 20 statute, is the one that maximizes net benefits to so-
 21 ciety.

22 “(2) If an agency’s interpretation of a statute cannot
 23 be affirmed under paragraph (1), the reviewing court shall
 24 find that the agency’s interpretation is arbitrary and ca-
 25 pricious.

1 ~~“SUBCHAPTER IV—EXECUTIVE OVERSIGHT~~

2 ~~“§ 651. Procedures~~

3 ~~“The President shall—~~

4 ~~“(1) establish procedures for agency compliance~~
 5 ~~with subchapters II and III; and~~

6 ~~“(2) monitor, review, and ensure agency imple-~~
 7 ~~mentation of such procedures.~~

8 ~~“§ 652. Promulgation and adoption~~

9 ~~“(a) Procedures established pursuant to section 651~~
 10 ~~shall only be implemented after opportunity for public~~
 11 ~~comment. Any such procedures shall be consistent with the~~
 12 ~~prompt completion of rulemaking proceedings.~~

13 ~~“(b)(1) If procedures established pursuant to section~~
 14 ~~651 include review of preliminary or final regulatory anal-~~
 15 ~~yses to ensure that they comply with subchapters II and~~
 16 ~~III, the time for any such review of a preliminary regu-~~
 17 ~~latory analysis shall not exceed 30 days following the re-~~
 18 ~~ceipt of the analysis by the President or by an officer to~~
 19 ~~whom the authority granted under section 651 has been~~
 20 ~~delegated pursuant to section 653.~~

21 ~~“(2) The time for review of a final regulatory analysis~~
 22 ~~shall not exceed 30 days following the receipt of the analy-~~
 23 ~~sis by the President or such officer.~~

1 “(3)(A) The times for each such review may be ex-
 2 tended for good cause by the President or such officer for
 3 an additional 30 days.

4 “(B) Notice of any such extension, together with a
 5 succinct statement of the reasons therefor, shall be in-
 6 serted in the rulemaking file.

7 **“§ 653. Delegation of authority**

8 “(a) The President may delegate the authority grant-
 9 ed by this subchapter to the Vice President or to an officer
 10 within the Executive Office of the President whose ap-
 11 pointment has been subject to the advice and consent of
 12 the Senate.

13 “(b)(1) Notice of any delegation, or any revocation
 14 or modification thereof, shall be published in the Federal
 15 Register.

16 “(2) Any notice with respect to a delegation to the
 17 Vice President shall contain a statement by the Vice Presi-
 18 dent that the Vice President will make every reasonable
 19 effort to respond to congressional inquiries concerning the
 20 exercise of the authority delegated under this section.

21 **“§ 654. Applicability**

22 ““The authority granted under this subchapter shall
 23 not apply to rules issued by the Nuclear Regulatory Com-
 24 mission.

1 **~~“§ 655. Judicial review~~**

2 ~~“The exercise of the authority granted under this~~
 3 ~~subchapter by the President or by an officer to whom such~~
 4 ~~authority has been delegated under section 653 shall not~~
 5 ~~be subject to judicial review in any manner under this~~
 6 ~~chapter.”.~~

7 ~~(b) JUDICIAL REVIEW OF REGULATORY FLEXIBILITY~~
 8 ~~ANALYSIS.—~~

9 ~~(1) AMENDMENT.—Section 611 of title 5, Unit-~~
 10 ~~ed States Code, is amended to read as follows:~~

11 **~~“§ 611. Judicial review~~**

12 ~~“(a)(1) Except as provided in paragraph (2), not~~
 13 ~~later than 1 year after the effective date of a final rule~~
 14 ~~with respect to which an agency—~~

15 ~~“(A) certified, pursuant to section 605(b), that~~
 16 ~~such rule would not have a significant economic im-~~
 17 ~~pact on a substantial number of small entities; or~~

18 ~~“(B) prepared final regulatory flexibility analy-~~
 19 ~~sis pursuant to section 604,~~

20 ~~an affected small entity may petition for the judicial re-~~
 21 ~~view of such certification or analysis in accordance with~~
 22 ~~this subsection. A court having jurisdiction to review such~~
 23 ~~rule for compliance with section 553 of this title or under~~
 24 ~~any other provision of law shall have jurisdiction to review~~
 25 ~~such certification or analysis.~~

1 ~~“(2)(A) Except as provided in subparagraph (B), in~~
 2 ~~the case of a provision of law that requires that an action~~
 3 ~~challenging a final agency regulation be commenced before~~
 4 ~~the expiration of the 1-year period provided in paragraph~~
 5 ~~(1), such lesser period shall apply to a petition for the~~
 6 ~~judicial review under this subsection.~~

7 ~~“(B) In a case in which an agency delays the issuance~~
 8 ~~of a final regulatory flexibility analysis pursuant to section~~
 9 ~~608(b), a petition for judicial review under this subsection~~
 10 ~~shall be filed not later than—~~

11 ~~“(i) 1 year; or~~

12 ~~“(ii) in a case in which a provision of law re-~~
 13 ~~quires that an action challenging a final agency reg-~~
 14 ~~ulation be commenced before the expiration of the 1-~~
 15 ~~year period provided in paragraph (1), the number~~
 16 ~~of days specified in such provision of law,~~
 17 ~~after the date the analysis is made available to the public.~~

18 ~~“(3) For purposes of this subsection, the term ‘af-~~
 19 ~~ected small entity’ means a small entity that is or will~~
 20 ~~be adversely affected by the final rule.~~

21 ~~“(4) Nothing in this subsection shall be construed to~~
 22 ~~affect the authority of any court to stay the effective date~~
 23 ~~of any rule or provision thereof under any other provision~~
 24 ~~of law.~~

1 “(5)(A) In a case in which an agency certifies that
2 such rule would not have a significant economic impact
3 on a substantial number of small entities, the court may
4 order the agency to prepare a final regulatory flexibility
5 analysis pursuant to section 604 if the court determines,
6 on the basis of the rulemaking record, that the certifi-
7 cation was arbitrary, capricious, an abuse of discretion,
8 or otherwise not in accordance with law.

9 “(B) In a case in which the agency prepared a final
10 regulatory flexibility analysis, the court may order the
11 agency to take corrective action consistent with section
12 604 if the court determines, on the basis of the rulemaking
13 record, that the final regulatory flexibility analysis was
14 prepared by the agency without complying with section
15 604.

16 “(6) If, by the end of the 90-day period beginning
17 on the date of the order of the court pursuant to para-
18 graph (5) (or such longer period as the court may pro-
19 vide), the agency fails, as appropriate—

20 “(A) to prepare the analysis required by section
21 604; or

22 “(B) to take corrective action consistent with
23 section 604 of this title,
24 the court may stay the rule or grant such other relief as
25 it deems appropriate.

1 ~~“(7) In making any determination or granting any~~
 2 ~~relief authorized by this subsection, the court shall take~~
 3 ~~due account of the rule of prejudicial error.~~

4 ~~“(b) In an action for the judicial review of a rule,~~
 5 ~~any regulatory flexibility analysis for such rule (including~~
 6 ~~an analysis prepared or corrected pursuant to subsection~~
 7 ~~(a)(5)) shall constitute part of the whole record of agency~~
 8 ~~action in connection with such review.~~

9 ~~“(c) Nothing in this section bars judicial review of~~
 10 ~~any other impact statement or similar analysis required~~
 11 ~~by any other law if judicial review of such statement or~~
 12 ~~analysis is otherwise provided by law.”.~~

13 ~~(2) EFFECTIVE DATE.—The amendment made~~
 14 ~~by paragraph (1) shall take effect on the date of en-~~
 15 ~~actment of this Act, except that the judicial review~~
 16 ~~authorized by section 611(a) of title 5, United~~
 17 ~~States Code (as added by subsection (a)), shall apply~~
 18 ~~only to final agency rules issued after the date of en-~~
 19 ~~actment of this Act.~~

20 ~~(c) PRESIDENTIAL AUTHORITY.—Nothing in this Act~~
 21 ~~shall limit the exercise by the President of the authority~~
 22 ~~and responsibility that the President otherwise possesses~~
 23 ~~under the Constitution and other laws of the United~~
 24 ~~States with respect to regulatory policies, procedures, and~~
 25 ~~programs of departments, agencies, and offices.~~

1 (d) ~~TECHNICAL AND CONFORMING AMENDMENTS.—~~

2 (1) Part I of title 5, United States Code, is amended by
3 striking out the chapter heading and table of sections for
4 chapter 6 and inserting in lieu thereof the following:

5 **“CHAPTER 6—THE ANALYSIS OF**
6 **REGULATORY FUNCTIONS**

 “SUBCHAPTER I—REGULATORY ANALYSIS

“Sec.

“601. Definitions.

“602. Regulatory agenda.

“603. Initial regulatory flexibility analysis.

“604. Final regulatory flexibility analysis.

“605. Avoidance of duplicative or unnecessary analyses.

“606. Effect on other law.

“607. Preparation of analyses.

“608. Procedure for waiver or delay of completion.

“609. Procedures for gathering comments.

“610. Periodic review of rules.

“611. Judicial review.

“612. Reports and intervention rights.

 “SUBCHAPTER II—ANALYSIS OF AGENCY PROPOSALS

“621. Definitions.

“622. Rulemaking cost-benefit analysis.

“623. Decisional criteria.

“624. Judicial review.

“625. Petition for cost-benefit analysis.

“626. Effective date of final regulations.

“627. Unauthorized rulemakings.

“628. Standard for review of agency interpretations of an enabling statute.

 “SUBCHAPTER III—RISK ASSESSMENTS

“631. Definitions.

“632. Applicability.

“633. Rule of construction.

“634. Requirement to prepare risk assessments.

“635. Principles for risk assessment.

“636. Principles for risk characterization and communication.

“637. Regulations; plan for assessing new information.

“638. Decisional criteria.

“639. Regulatory priorities.

“640. Establishment of program.

 “SUBCHAPTER IV—EXECUTIVE OVERSIGHT

“651. Procedures.

“652. Promulgation and adoption.
 “653. Delegation of authority.
 “654. Applicability.
 “655. Judicial review.”.

1 ~~(2) Chapter 6 of title 5, United States Code, is~~
 2 amended by inserting immediately before section 601, the
 3 following subchapter heading:

4 “~~SUBCHAPTER I—REGULATORY ANALYSIS~~”.

5 ***[SECTION 1. SHORT TITLE.***

6 ***[This Act may be cited as the “Comprehensive Regu-***
 7 *latory Reform Act of 1995”.*

8 ***[SEC. 2. DEFINITIONS.***

9 ***[Section 551 of title 5, United States Code, is amend-***
 10 *ed—*

11 ***[(1) in paragraph (13), by striking out “; and”***
 12 *and inserting in lieu thereof a semicolon;*

13 ***[(2) in paragraph (14), by striking out the pe-***
 14 *riod and inserting in lieu thereof “; and”; and*

15 ***[(3) by adding at the end thereof the following***
 16 *new paragraph:*

17 ***[(“(15) ‘Director’ means the Director of the Of-***
 18 *fice of Management and Budget.”.*

19 ***[SEC. 3. ANALYSIS OF AGENCY RULES.***

20 ***[(a) IN GENERAL.—Chapter 6 of title 5, United***
 21 *States Code, is amended by adding at the end the following:*

1 **【“SUBCHAPTER II—ANALYSIS OF AGENCY RULES**

2 **【“§621. Definitions**

3 **【“For purposes of this subchapter the definitions**
 4 **under section 551 shall apply and—**

5 **【“(1) the term ‘benefit’ means the reasonably**
 6 **identifiable significant favorable effects, including so-**
 7 **cial, environmental and economic benefits, that are**
 8 **expected to result directly or indirectly from imple-**
 9 **mentation of a rule or an alternative to a rule;**

10 **【“(2) the term ‘cost’ means the reasonably iden-**
 11 **tifiable significant adverse effects, including social,**
 12 **environmental, and economic costs that are expected**
 13 **to result directly or indirectly from implementation**
 14 **of, or compliance with, a rule or an alternative to a**
 15 **rule;**

16 **【“(3) the term ‘cost-benefit analysis’ means an**
 17 **evaluation of the costs and benefits of a rule, quan-**
 18 **tified to the extent feasible and appropriate and oth-**
 19 **erwise qualitatively described, that is prepared in ac-**
 20 **cordance with the requirements of this subchapter at**
 21 **the level of detail appropriate and practicable for rea-**
 22 **soned decisionmaking on the matter involved, taking**
 23 **into consideration the significance and complexity of**
 24 **the decision and any need for expedition;**

25 **【“(4)(A) the term ‘major rule’ means—**

1 **[(i)** *a rule or a group of closely related*
 2 *rules that the agency proposing the rule, the Di-*
 3 *rector, or a designee of the President reasonably*
 4 *determines is likely to have a gross annual effect*
 5 *on the economy of \$100,000,000 or more in rea-*
 6 *sonably quantifiable direct and indirect costs; or*

7 **[(ii)** *a rule or a group of closely related*
 8 *rules that is otherwise determined to be a major*
 9 *rule by the agency proposing the rule, the Direc-*
 10 *tor, or a designee of the President on the ground*
 11 *that the rule is likely to result in—*

12 **[(I)** *a substantial increase in costs or*
 13 *prices for wage earners, consumers, individ-*
 14 *ual industries, nonprofit organizations,*
 15 *Federal, State, local, or tribal government*
 16 *agencies, or geographic regions;*

17 **[(II)** *significant adverse effects on*
 18 *wages, economic growth, investment, pro-*
 19 *ductivity, innovation, the environment,*
 20 *public health or safety, or the ability of en-*
 21 *terprises whose principal places of business*
 22 *are in the United States to compete in do-*
 23 *mestic or export markets;*

1 **¶**“(III) a serious inconsistency or in-
 2 interference with an action taken or planned
 3 by another agency;

4 **¶**“(IV) the material alteration of the
 5 budgetary impact of entitlements, grants,
 6 user fees, or loan programs, or the rights
 7 and obligations of recipients thereof; or

8 **¶**“(V) a significant impact on a sector
 9 of the economy, or disproportionate costs to
 10 a class of persons and relatively severe eco-
 11 nomic, social, and environmental con-
 12 sequences for the class; and

13 **¶**“(B) the term ‘major rule’ shall not include—

14 **¶**“(i) a rule that involves the internal reve-
 15 nue laws of the United States;

16 **¶**“(ii) a rule or agency action that author-
 17 izes the introduction into, or removal from, com-
 18 merce, or recognizes the marketable status, of a
 19 product; or

20 **¶**“(iii) a rule exempt from notice and pub-
 21 lic comment procedure under section 553 of this
 22 title;

23 **¶**“(5) the term ‘market-based mechanism’ means
 24 a regulatory program that—

1 **[(A)** *imposes legal accountability for the*
 2 *achievement of an explicit regulatory objective,*
 3 *including the reduction of environmental pollut-*
 4 *ants or of risks to human health, safety, or the*
 5 *environment, on each regulated person;*

6 **[(B)** *affords maximum flexibility to each*
 7 *regulated person in complying with mandatory*
 8 *regulatory objectives, and such flexibility shall,*
 9 *where feasible and appropriate, include the op-*
 10 *portunity to transfer to, or receive from, other*
 11 *persons, including for cash or other legal consid-*
 12 *eration, increments of compliance responsibility*
 13 *established by the program; and*

14 **[(C)** *permits regulated persons to respond*
 15 *at their own discretion in an automatic manner,*
 16 *consistent with subparagraph (B), to changes in*
 17 *general economic conditions and in economic cir-*
 18 *cumstances directly pertinent to the regulatory*
 19 *program without affecting the achievement of the*
 20 *program's explicit regulatory mandates under*
 21 *subparagraph (A);*

22 **[(6)** *the term 'performance standard' means a*
 23 *requirement that imposes legal accountability for the*
 24 *achievement of an explicit regulatory objective, such*
 25 *as the reduction of environmental pollutants or of*

1 *risks to human health, safety, or the environment, on*
 2 *each regulated person;*

3 **¶**“(7) *the term ‘risk assessment’ has the same*
 4 *meaning as such term is defined under section 632(5);*
 5 *and*

6 **¶**“(8) *the term ‘rule’ has the same meaning as*
 7 *in section 551(4) of this title, and shall not include—*

8 **¶**“(A) *a rule of particular applicability*
 9 *that approves or prescribes for the future rates,*
 10 *wages, prices, services, corporate or financial*
 11 *structures, reorganizations, mergers, acquisitions,*
 12 *accounting practices, or disclosures bearing on*
 13 *any of the foregoing;*

14 **¶**“(B) *a rule relating to monetary policy*
 15 *proposed or promulgated by the Board of Gov-*
 16 *ernors of the Federal Reserve System or by the*
 17 *Federal Open Market Committee;*

18 **¶**“(C) *a rule relating to the safety or sound-*
 19 *ness of federally insured depository institutions*
 20 *or any affiliate of such an institution (as defined*
 21 *in section 2(k) of the Bank Holding Company*
 22 *Act of 1956 (12 U.S.C. 1841(k)); credit unions;*
 23 *the Federal Home Loan Banks; government-*
 24 *sponsored housing enterprises; a Farm Credit*
 25 *System Institution; foreign banks, and their*

branches, agencies, commercial lending companies or representative offices that operate in the United States and any affiliate of such foreign banks (as those terms are defined in the International Banking Act of 1978 (12 U.S.C. 3101)); or a rule relating to the payments system or the protection of deposit insurance funds or Farm Credit Insurance Fund; or

“(D) a rule issued by the Federal Election Commission or a rule issued by the Federal Communications Commission pursuant to sections 312(a)(7) and 315 of the Communications Act of 1934.

“§ 622. Rulemaking cost-benefit analysis

“(a) Before publishing notice of a proposed rulemaking for any rule (or, in the case of a notice of a proposed rulemaking that has been published on or before the effective date of this subchapter, no later than 30 days after such date), each agency shall determine whether the rule is or is not a major rule within the meaning of section 621(4)(A)(i) and, if it is not, determine whether it is a major rule under section 621(4)(A)(ii). For the purpose of any such determination, a group of closely related rules shall be considered as one rule.

1 **¶**“(b)(1) If an agency has determined that a rule is
2 not a major rule, the Director or a designee of the President
3 may, as appropriate, determine that the rule is a major
4 rule no later than 30 days after the publication of the notice
5 of proposed rulemaking for the rule (or, in the case of a
6 notice of proposed rulemaking that has been published on
7 or before the effective date of this subchapter, no later than
8 60 days after such date).

9 **¶**“(2) Such determination shall be published in the
10 Federal Register, together with a succinct statement of the
11 basis for the determination.

12 **¶**“(c)(1)(A) When the agency publishes a notice of pro-
13 posed rulemaking for a major rule, the agency shall issue
14 and place in the rulemaking file an initial cost-benefit
15 analysis, and shall include a summary of such analysis in
16 the notice of proposed rulemaking.

17 **¶**“(B)(i) When the Director or a designee of the Presi-
18 dent has published a determination that a rule is a major
19 rule after the publication of the notice of proposed rule-
20 making for the rule, the agency shall promptly issue and
21 place in the rulemaking file an initial cost-benefit analysis
22 for the rule and shall publish in the Federal Register a sum-
23 mary of such analysis.

24 **¶**“(ii) Following the issuance of an initial cost-benefit
25 analysis under clause (i), the agency shall give interested

1 *persons an opportunity to comment pursuant to section 553*
2 *in the same manner as if the draft cost-benefit analysis had*
3 *been issued with the notice of proposed rulemaking.*

4 **¶**“(2) *Each initial cost-benefit analysis shall con-*
5 *tain—*

6 **¶**“(A) *an analysis of the benefits of the proposed*
7 *rule, including any benefits that cannot be quantified,*
8 *and an explanation of how the agency anticipates*
9 *that such benefits will be achieved by the proposed*
10 *rule, including a description of the persons or classes*
11 *of persons likely to receive such benefits;*

12 **¶**“(B) *an analysis of the costs of the proposed*
13 *rule, including any costs that cannot be quantified,*
14 *and an explanation of how the agency anticipates*
15 *that such costs will result from the proposed rule, in-*
16 *cluding a description of the persons or classes of per-*
17 *sons likely to bear such costs;*

18 **¶**“(C) *an identification (including an analysis*
19 *of costs and benefits) of an appropriate number of*
20 *reasonable alternatives allowed under the statute*
21 *granting the rulemaking authority for achieving the*
22 *identified benefits of the proposed rule, including al-*
23 *ternatives that—*

24 **¶**“(i) *require no government action;*

1 **【**“(ii) will accommodate differences among
 2 geographic regions and among persons with dif-
 3 fering levels of resources with which to comply;
 4 and

5 **【**“(iii) employ voluntary programs, per-
 6 formance standards, or market-based mecha-
 7 nisms that permit greater flexibility in achieving
 8 the identified benefits of the proposed rule and
 9 that comply with the requirements of subpara-
 10 graph (D);

11 **【**“(D) an assessment of the feasibility of estab-
 12 lishing a regulatory program that operates through
 13 the application of market-based mechanisms;

14 **【**“(E) an explanation of the extent to which the
 15 proposed rule—

16 **【**“(i) will accommodate differences among
 17 geographic regions and among persons with dif-
 18 fering levels of resources with which to comply;
 19 and

20 **【**“(ii) employs voluntary programs, per-
 21 formance standards, or market-based mecha-
 22 nisms that permit greater flexibility in achieving
 23 the identified benefits of the proposed rule;

24 **【**“(F) a description of the quality, reliability,
 25 and relevance of scientific or economic evaluations or

1 *information in accordance with the cost-benefit anal-*
 2 *ysis and risk assessment requirements of this chapter;*

3 **¶**“(G) if not expressly or implicitly inconsistent
 4 *with the statute under which the agency is proposing*
 5 *the rule, an explanation of the extent to which the*
 6 *identified benefits of the proposed rule justify the*
 7 *identified costs of the proposed rule, and an expla-*
 8 *nation of how the proposed rule is likely to substan-*
 9 *tially achieve the rulemaking objectives in a more*
 10 *cost-effective manner than the alternatives to the pro-*
 11 *posed rule, including alternatives identified in ac-*
 12 *cordance with subparagraph (C); and*

13 **¶**“(H) if a major rule subject to subchapter III
 14 *addresses risks to human health, safety, or the envi-*
 15 *ronment—*

16 **¶**“(i) a risk assessment in accordance with
 17 *this chapter; and*

18 **¶**“(ii) for each such proposed or final rule,
 19 *an assessment of incremental risk reduction or*
 20 *other benefits associated with each significant*
 21 *regulatory alternative considered by the agency*
 22 *in connection with the rule or proposed rule.*

23 **¶**“(d)(1) *When the agency publishes a final major rule,*
 24 *the agency shall also issue and place in the rulemaking file*

1 *a final cost-benefit analysis, and shall include a summary*
 2 *of the analysis in the statement of basis and purpose.*

3 **¶**“(2) *Each final cost-benefit analysis shall contain—*

4 **¶**“(A) *a description and comparison of the bene-*
 5 *fits and costs of the rule and of the reasonable alter-*
 6 *natives to the rule described in the rulemaking, in-*
 7 *cluding the market-based mechanisms identified*
 8 *under subsection (c)(2)(C)(iii); and*

9 **¶**“(B) *if not expressly or implicitly inconsistent*
 10 *with the statute under which the agency is acting, a*
 11 *reasonable determination, based upon the rulemaking*
 12 *file considered as a whole, whether—*

13 **¶**“(i) *the benefits of the rule justify the costs*
 14 *of the rule; and*

15 **¶**“(ii) *the rule will achieve the rulemaking*
 16 *objectives in a more cost-effective manner than*
 17 *the alternatives described in the rulemaking, in-*
 18 *cluding the market-based mechanisms identified*
 19 *under subsection (c)(2)(C)(iii).*

20 **¶**“(e)(1) *The analysis of the benefits and costs of a pro-*
 21 *posed and a final rule required under this section shall in-*
 22 *clude, to the extent feasible, a quantification or numerical*
 23 *estimate of the quantifiable benefits and costs. Such quan-*
 24 *tification or numerical estimate shall be made in the most*
 25 *appropriate units of measurement, using comparable as-*

1 *sumptions, including time periods, shall specify the ranges*
 2 *of predictions, and shall explain the margins of error in-*
 3 *volved in the quantification methods and in the estimates*
 4 *used. An agency shall describe the nature and extent of the*
 5 *nonquantifiable benefits and costs of a final rule pursuant*
 6 *to this section in as precise and succinct a manner as pos-*
 7 *sible. An agency shall not be required to make such evalua-*
 8 *tion primarily on a mathematical or numerical basis.*

9 **¶**“(2)(A) *In evaluating and comparing costs and bene-*
 10 *fits and in evaluating the risk assessment information de-*
 11 *veloped under subchapter III, the agency shall not rely on*
 12 *cost, benefit, or risk assessment information that is not ac-*
 13 *companied by data, analysis, or other supporting materials*
 14 *that would enable the agency and other persons interested*
 15 *in the rulemaking to assess the accuracy, reliability, and*
 16 *uncertainty factors applicable to such information.*

17 **¶**“(B) *The agency evaluations of the relationships of*
 18 *the benefits of a proposed and final rule to its costs shall*
 19 *be clearly articulated in accordance with this section.*

20 **¶**“(f) *As part of the promulgation of each major rule*
 21 *that addresses risks to human health, safety, or the environ-*
 22 *ment, the head of the agency or the President shall make*
 23 *a determination that—*

24 **¶**“(1) *the risk assessment and the analysis under*
 25 *subsection (c)(2)(H) are based on a scientific evalua-*

1 *tion of the risk addressed by the major rule and that*
2 *the conclusions of such evaluation are supported by*
3 *the available information; and*

4 **¶**“(2) *the regulatory alternative chosen will re-*
5 *duce risk in a cost-effective and, to the extent feasible,*
6 *flexible manner, taking into consideration any of the*
7 *alternatives identified under subsection (c)(2) (C) and*
8 *(D).*

9 **¶**“(g) *The preparation of the initial or final cost-bene-*
10 *fit analysis required by this section shall only be performed*
11 *under the direction of an officer or employee of the agency.*
12 *The preceding sentence shall not preclude a person outside*
13 *the agency from gathering data or information to be used*
14 *by the agency in preparing any such cost-benefit analysis*
15 *or from providing an explanation sufficient to permit the*
16 *agency to analyze such data or information. If any such*
17 *data or information is gathered or explained by a person*
18 *outside the agency, the agency shall specifically identify in*
19 *the initial or final cost-benefit analysis the data or infor-*
20 *mation gathered or explained and the person who gathered*
21 *or explained it, and shall describe the arrangement by*
22 *which the information was procured by the agency, includ-*
23 *ing the total amount of funds expended for such procure-*
24 *ment.*

1 **█**“(h) The requirements of this subchapter shall not
 2 alter the criteria for rulemaking otherwise applicable under
 3 other statutes.

4 **█**“**§623. Judicial review**

5 **█**“(a) Compliance or noncompliance by an agency
 6 with the provisions of this subchapter and subchapter III
 7 shall not be subject to judicial review except in connection
 8 with review of a final agency rule and according to the pro-
 9 visions of this section.

10 **█**“(b) Any determination by a designee of the Presi-
 11 dent or the Director that a rule is, or is not, a major rule
 12 shall not be subject to judicial review in any manner.

13 **█**“(c) The determination by an agency that a rule is,
 14 or is not, a major rule under section 621(4)(A)(i) shall be
 15 set aside by a reviewing court only upon a clear and con-
 16 vincing showing that the determination is erroneous in
 17 light of the information available to the agency at the time
 18 the agency made the determination. Any determination by
 19 an agency that a rule is, or is not, a major rule under
 20 section 621(4)(A)(ii) shall not be subject to judicial review
 21 in any manner.

22 **█**“(d) If the cost-benefit analysis or risk assessment re-
 23 quired under this chapter has been wholly omitted for any
 24 major rule, a court shall vacate the rule and remand the
 25 case for further consideration. If an analysis or assessment

1 *has been performed, the court shall not review to determine*
 2 *whether the analysis or assessment conformed to the par-*
 3 *ticular requirements of this chapter.*

4 **¶**“(e) *Any cost-benefit analysis or risk assessment pre-*
 5 *pared under this chapter shall not be subject to judicial con-*
 6 *sideration separate or apart from review of the agency ac-*
 7 *tion to which it relates. When an action for judicial review*
 8 *of an agency action is instituted, any regulatory analysis*
 9 *for such agency action shall constitute part of the whole*
 10 *administrative record of agency action for the purpose of*
 11 *judicial review of the agency action, and shall, to the extent*
 12 *relevant, be considered by a court in determining the legal-*
 13 *ity of the agency action.*

14 **¶“§624. Deadlines for rulemaking**

15 **¶**“(a) *All deadlines in statutes that require agencies*
 16 *to propose or promulgate any rule subject to section 622*
 17 *or subchapter III during the 2-year period beginning on*
 18 *the effective date of this section shall be suspended until the*
 19 *earlier of—*

20 **¶**“(1) *the date on which the requirements of sec-*
 21 *tion 622 or subchapter III are satisfied; or*

22 **¶**“(2) *the date occurring 6 months after the date*
 23 *of the applicable deadline.*

24 **¶**“(b) *All deadlines imposed by any court of the United*
 25 *States that would require an agency to propose or promul-*

1 *gate a rule subject to section 622 or subchapter III during*
 2 *the 2-year period beginning on the effective date of this sec-*
 3 *tion shall be suspended until the earlier of—*

4 **¶**“(1) *the date on which the requirements of sec-*
 5 *tion 622 or subchapter III are satisfied; or*

6 **¶**“(2) *the date occurring 6 months after the date*
 7 *of the applicable deadline.*

8 **¶**“(c) *In any case in which the failure to promulgate*
 9 *a rule by a deadline occurring during the 2-year period*
 10 *beginning on the effective date of this section would create*
 11 *an obligation to regulate through individual adjudications,*
 12 *the deadline shall be suspended until the earlier of—*

13 **¶**“(1) *the date on which the requirements of sec-*
 14 *tion 622 or subchapter III are satisfied; or*

15 **¶**“(2) *the date occurring 6 months after the date*
 16 *of the applicable deadline.*

17 **¶“§ 625. Agency review of rules**

18 **¶**“(a)(1)(A) *No later than 9 months after the effective*
 19 *date of this section, each agency shall prepare and publish*
 20 *in the Federal Register a proposed schedule for the review,*
 21 *in accordance with this section, of—*

22 **¶**“(i) *each rule of the agency that is in effect on*
 23 *such effective date and which, if adopted on such ef-*
 24 *fective date, would be a major rule; and*

1 **¶**“(ii) each rule of the agency in effect on the ef-
 2 fective date of this section (in addition to the rules de-
 3 scribed in clause (i)) that the agency has selected for
 4 review.

5 **¶**“(B) Each proposed schedule required under sub-
 6 paragraph (A) shall be developed in consultation with—

7 **¶**“(i) the Administrator of the Office of Informa-
 8 tion and Regulatory Affairs; and

9 **¶**“(ii) the classes of persons affected by the rules,
 10 including members from the regulated industries,
 11 small businesses, State and local governments, and or-
 12 ganizations representing the interested public.

13 **¶**“(C) Each proposed schedule required under sub-
 14 paragraph (A) shall establish priorities for the review of
 15 rules that, in the joint determination of the Administrator
 16 of the Office of Information and Regulatory Affairs and the
 17 agency, most likely can be amended or eliminated to—

18 **¶**“(i) provide the same or greater benefits at sub-
 19 stantially lower costs;

20 **¶**“(ii) achieve substantially greater benefits at
 21 the same or lower costs; or

22 **¶**“(iii) replace command-and-control regulatory
 23 requirements with market mechanisms or performance
 24 standards that achieve substantially equivalent bene-
 25 fits at lower costs or with greater flexibility.

1 **¶**“(D) *Each proposed schedule required by subpara-*
 2 *graph (A) shall include—*

3 **¶**“(i) *a brief explanation of the reasons the agen-*
 4 *cy considers each rule on the schedule to be a major*
 5 *rule, or the reasons why the agency selected the rule*
 6 *for review;*

7 **¶**“(ii) *a date set by the agency, in accordance*
 8 *with subsection (b), for the completion of the review*
 9 *of each such rule; and*

10 **¶**“(iii) *a statement that the agency requests com-*
 11 *ments from the public on the proposed schedule.*

12 **¶**“(E) *The agency shall set a date to initiate review*
 13 *of each rule on the schedule in a manner that will ensure*
 14 *the simultaneous review of related items and that will*
 15 *achieve a reasonable distribution of reviews over the period*
 16 *of time covered by the schedule.*

17 **¶**“(2) *No later than 90 days before publishing in the*
 18 *Federal Register the proposed schedule required under para-*
 19 *graph (1), each agency shall make the proposed schedule*
 20 *available to the Director or a designee of the President. The*
 21 *President or that officer may select for review in accordance*
 22 *with this section any additional rule.*

23 **¶**“(3) *No later than 1 year after the effective date of*
 24 *this section, each agency shall publish in the Federal Reg-*
 25 *ister a final schedule for the review of the rules referred*

1 *to in paragraphs (1) and (2). Each agency shall publish*
 2 *with the final schedule the response of the agency to com-*
 3 *ments received concerning the proposed schedule.*

4 **¶**“(b)(1) *Except as explicitly provided otherwise by*
 5 *statute, the agency shall, pursuant to subsections (c)*
 6 *through (e), review—*

7 **¶**“(A) *each rule on the schedule promulgated*
 8 *pursuant to subsection (a);*

9 **¶**“(B) *each major rule promulgated, amended, or*
 10 *otherwise continued by an agency after the effective*
 11 *date of this section; and*

12 **¶**“(C) *each rule promulgated after the effective*
 13 *date of this section that the President or the officer*
 14 *designated by the President selects for review pursu-*
 15 *ant to subsection (a)(2).*

16 **¶**“(2) *Except as provided pursuant to subsection (f),*
 17 *the review of a rule required by this section shall be com-*
 18 *pleted no later than the later of—*

19 **¶**“(A) *10 years after the effective date of this sec-*
 20 *tion; or*

21 **¶**“(B) *10 years after the date on which the rule*
 22 *is—*

23 **¶**“(i) *promulgated; or*

24 **¶**“(ii) *amended or continued under this sec-*
 25 *tion.*

1 **¶**“(c) An agency shall publish in the Federal Register
 2 a notice of its proposed action under this section with re-
 3 spect to a rule being reviewed. The notice shall include—

4 **¶**“(1) an identification of the specific statutory
 5 authority under which the rule was promulgated and
 6 an explanation of whether the agency’s interpretation
 7 of the statute is expressly required by the current text
 8 of that statute or, if not, whether it is within the
 9 range of permissible interpretations of the statute;

10 **¶**“(2) an analysis of the benefits and costs of the
 11 rule during the period in which it has been in effect;

12 **¶**“(3) an explanation of the proposed agency ac-
 13 tion with respect to the rule, including action to re-
 14 peal or amend the rule to resolve inconsistencies or
 15 conflicts with any other obligation or requirement es-
 16 tablished by any Federal statute, rule, or other agency
 17 statement, interpretation, or action that has the force
 18 of law; and

19 **¶**“(4) a statement that the agency seeks propos-
 20 als from the public for modifications or alternatives
 21 to the rule which may accomplish the objectives of the
 22 rule in a more effective or less burdensome manner.

23 **¶**“(d) If an agency proposes to repeal or amend a rule
 24 under review pursuant to this section, the agency shall,
 25 after issuing the notice required by subsection (c), comply

1 *with the provisions of this chapter, chapter 5, and any other*
 2 *applicable law. The requirements of such provisions and re-*
 3 *lated requirements shall apply to the same extent and in*
 4 *the same manner as in the case of a proposed agency action*
 5 *to repeal or amend a rule that is not taken pursuant to*
 6 *the review required by this section.*

7 **¶**“(e) *If an agency proposes to continue without*
 8 *amendment a rule under review pursuant to this section,*
 9 *the agency shall—*

10 **¶**“(1) *give interested persons no less than 60*
 11 *days after the publication of the notice required by*
 12 *subsection (c) to comment on the proposed continu-*
 13 *ation; and*

14 **¶**“(2) *publish in the Federal Register notice of*
 15 *the continuation of such rule.*

16 **¶**“(f) *Any agency, which for good cause finds that com-*
 17 *pliance with this section with respect to a particular rule*
 18 *during the period provided in subsection (b) of this section*
 19 *is contrary to an important public interest may request the*
 20 *President, or the officer designated by the President pursu-*
 21 *ant to subsection (a)(2), to establish a period longer than*
 22 *10 years for the completion of the review of such rule. The*
 23 *President or that officer may extend the period for review*
 24 *of a rule to a total period of no more than 15 years. Such*

1 *extension shall be published in the Federal Register with*
 2 *an explanation of the reasons therefor.*

3 **¶**“(g) *If the agency fails to comply with the require-*
 4 *ments of subsection (b)(2), the rule for which rulemaking*
 5 *proceedings have not been completed shall cease to be en-*
 6 *forceable against any person.*

7 **¶**“(h) *Nothing in this section shall relieve any agency*
 8 *from its obligation to respond to a petition to issue, amend,*
 9 *or repeal a rule, for an interpretation regarding the mean-*
 10 *ing of a rule, or for a variance or exemption from the terms*
 11 *of a rule, submitted pursuant to any other provision of law.*

12 **¶“§626. Public participation and accountability**

13 **¶**“*In order to maximize accountability for, and public*
 14 *participation in, the development and review of regulatory*
 15 *actions each agency shall, consistent with chapter 5 and*
 16 *other applicable law, provide the public with opportunities*
 17 *for meaningful participation in the development of regu-*
 18 *latory actions, including—*

19 **¶**“(1) *seeking the involvement, where practicable*
 20 *and appropriate, of those who are intended to benefit*
 21 *from and those who are expected to be burdened by*
 22 *any regulatory action;*

23 **¶**“(2) *providing in any proposed or final rule-*
 24 *making notice published in the Federal Register—*

1 **【**“(A) a certification of compliance with the
 2 requirements of this chapter, or an explanation
 3 why such certification cannot be made;

4 **【**“(B) a summary of any regulatory analy-
 5 sis required under this chapter, or under any
 6 other legal requirement, and notice of the avail-
 7 ability of the regulatory analysis;

8 **【**“(C) a certification that the rule will
 9 produce benefits that will justify the cost to the
 10 Government and to the public of implementation
 11 of, and compliance with, the rule, or an expla-
 12 nation why such certification cannot be made;
 13 and

14 **【**“(D) a summary of the results of any reg-
 15 ulatory review and the agency’s response to such
 16 review, including an explanation of any signifi-
 17 cant changes made to such regulatory action as
 18 a consequence of regulatory review;

19 **【**“(3) identifying, upon request, a regulatory ac-
 20 tion and the date upon which such action was sub-
 21 mitted to the designated officer to whom authority
 22 was delegated under section 644 for review;

23 **【**“(4) disclosure to the public, consistent with
 24 section 634(3), of any information created or collected
 25 in performing a regulatory analysis required under

1 *this chapter, or under any other legal requirement;*
 2 *and*

3 **【“(5) placing in the appropriate rulemaking**
 4 *record all written communications received from the*
 5 *Director, other designated officer, or other individual*
 6 *or entity relating to regulatory review.*

7 **【“SUBCHAPTER III—RISK ASSESSMENTS**

8 **【“§631. Findings and purposes**

9 **【“(a) The Congress finds that:**

10 **【“(1) Environmental, health, and safety regula-**
 11 *tions have lead to dramatic improvements in the en-*
 12 *vironment and have significantly reduced risks to*
 13 *human health; except—*

14 **【“(A) many regulations have been more**
 15 *costly and less effective than necessary; and*

16 **【“(B) too often, regulatory priorities have**
 17 *not been based upon a realistic consideration of*
 18 *risk, risk reduction opportunities, and costs.*

19 **【“(2) The public and private resources available**
 20 *to address health, safety, and environmental risks are*
 21 *not unlimited. Those resources should be allocated to*
 22 *address the greatest needs in the most cost-effective*
 23 *manner and to ensure that the incremental costs of*
 24 *regulatory options are reasonably related to the incre-*
 25 *mental benefits.*

1 **¶**“(3) To provide more cost-effective protection to
 2 human health, safety, and the environment, regu-
 3 latory priorities should be supported by realistic and
 4 plausible scientific risk assessments and risk manage-
 5 ment choices that are grounded in cost-benefit prin-
 6 ciples.

7 **¶**“(4) Risk assessment has proved to be a useful
 8 decisionmaking tool, except—

9 **¶**“(A) improvements are needed in both the
 10 quality of assessments and the characterization
 11 and communication of findings;

12 **¶**“(B) scientific and other data must be bet-
 13 ter collected, organized, and evaluated; and

14 **¶**“(C) the critical information resulting
 15 from a risk assessment must be effectively com-
 16 municated in an objective and unbiased manner
 17 to decision makers, and from decision makers to
 18 the public.

19 **¶**“(5) The public stakeholders should be involved
 20 in the decisionmaking process for regulating risks.
 21 The public has the right to know about the risks ad-
 22 dressed by regulation, the amount of risk reduced, the
 23 quality of the science used to support decisions, and
 24 the cost of implementing and complying with regula-
 25 tions. Such knowledge will allow for public scrutiny

1 *and will promote the quality, integrity, and respon-*
 2 *siveness of agency decisions.*

3 **¶**“(b) *The purposes of this subchapter are to—*

4 **¶**“(1) *present the public and executive branch*
 5 *with the most realistic and plausible information con-*
 6 *cerning the nature and magnitude of health, safety,*
 7 *and environmental risks to promote sound regulatory*
 8 *decisions and public education;*

9 **¶**“(2) *provide for full consideration and discus-*
 10 *sion of relevant data and potential methodologies;*

11 **¶**“(3) *require explanation of significant choices*
 12 *in the risk assessment process that will allow for bet-*
 13 *ter public understanding; and*

14 **¶**“(4) *improve consistency within the executive*
 15 *branch in preparing risk assessments and risk char-*
 16 *acterizations.*

17 **¶“§632. Definitions**

18 **¶**“*For purposes of this subchapter, the definitions*
 19 *under sections 551 and 621 shall apply and:*

20 **¶**“(1) *The term ‘covered agency’ means each of*
 21 *the following:*

22 **¶**“(A) *The Environmental Protection Agen-*
 23 *cy.*

24 **¶**“(B) *The Department of Labor.*

25 **¶**“(C) *The Department of Transportation.*

1 **【**“(D) *The Food and Drug Administration.*

2 **【**“(E) *The Department of Energy.*

3 **【**“(F) *The Department of the Interior.*

4 **【**“(G) *The Department of Agriculture.*

5 **【**“(H) *The Consumer Product Safety Com-*
6 *mission.*

7 **【**“(I) *The National Oceanic and Atmos-*
8 *pheric Administration.*

9 **【**“(J) *The United States Army Corps of*
10 *Engineers.*

11 **【**“(K) *The Nuclear Regulatory Commission.*

12 **【**“(L) *Any other Federal agency considered*
13 *a covered agency under section 633(b).*

14 **【**“(2) *The term ‘emergency’ means a situation*
15 *that is immediately impending and extraordinary in*
16 *nature, demanding attention due to a condition, cir-*
17 *cumstance or practice reasonably expected to cause*
18 *death, serious illness or severe injury to humans, or*
19 *substantial endangerment to private property or the*
20 *environment if no action is taken.*

21 **【**“(3) *The term ‘estimates of risk’ means numer-*
22 *ical representations of the potential magnitude of*
23 *harm to populations or the probability of harm to in-*
24 *dividuals, including, as appropriate, those derived by*
25 *considering the range and distribution of estimates of*

1 *dose-response (potency) and exposure, including ap-*
 2 *propriate statistical representation of the range and*
 3 *most likely exposure levels, and the identification of*
 4 *the populations or subpopulations addressed. When*
 5 *appropriate and practicable, a description of any*
 6 *populations or subpopulations that are likely to expe-*
 7 *rience exposures at the upper end of the distribution*
 8 *should be included.*

9 **【“(4) The term ‘hazard identification’ means**
 10 *identification of a substance, activity, or condition as*
 11 *potentially causing harm to human health, safety, or*
 12 *the environment.*

13 **【“(5) The term ‘risk assessment’ means—**

14 **【“(A) identifying, quantifying to the extent**
 15 *feasible and appropriate, and characterizing*
 16 *hazards and exposures to those hazards in order*
 17 *to provide structured information on the nature*
 18 *of threats to human health, safety, or the envi-*
 19 *ronment; and*

20 **【“(B) the document containing the expla-**
 21 *nation of how the assessment process has been*
 22 *applied to an individual substance, activity, or*
 23 *condition.*

24 **【“(6) The term ‘risk characterization’ means the**
 25 *integration, synthesis, and organization of hazard*

1 *identification, dose-response and exposure informa-*
2 *tion that addresses the needs of decision makers and*
3 *interested parties. The term includes both the process*
4 *and specific outputs, including—*

5 **■**“(A) *the element of a risk assessment that*
6 *involves presentation of the degree of risk in any*
7 *regulatory proposal or decision, report to Con-*
8 *gress, or other document that is made available*
9 *to the public; and*

10 **■**“(B) *discussions of uncertainties, conflict-*
11 *ing data, estimates of risk, extrapolations, infer-*
12 *ences, and opinions.*

13 **■**“(7) *The term ‘screening analysis’ means an*
14 *analysis that arrives at a qualitative estimate or a*
15 *bounding estimate of risk that permits the risk man-*
16 *ager to accept or reject some management options, or*
17 *permits establishing priorities for agency action. Such*
18 *term includes an assessment performed by a regulated*
19 *party and submitted to an agency under a regulatory*
20 *requirement.*

21 **■**“(8) *The term ‘substitution risk’ means a rea-*
22 *sonably likely increased risk to human health, safety,*
23 *or the environment from a regulatory option designed*
24 *to decrease other risks.*

1 **["§633. Applicability**

2 **["(a)** *Except as provided in subsection (c), this sub-*
 3 *chapter shall apply to all risk assessments and risk charac-*
 4 *terizations prepared by, or on behalf of, or prepared by oth-*
 5 *ers and adopted by any covered agency in connection with*
 6 *a major rule addressing health, safety, and environmental*
 7 *risks.*

8 **["(b)(1)** *No later than 18 months after the effective*
 9 *date of this section, the President, acting through the Direc-*
 10 *tor of the Office of Management and Budget, shall determine*
 11 *whether other Federal agencies should be considered covered*
 12 *agencies for the purposes of this subchapter. Such deter-*
 13 *mination, with respect to a particular Federal agency, shall*
 14 *be based on the impact of risk assessment documents and*
 15 *risk characterization documents on—*

16 **["(A)** *regulatory programs administered by that*
 17 *agency; and*

18 **["(B)** *the communication of risk information by*
 19 *that agency to the public.*

20 **["(2)** *If the President makes a determination under*
 21 *paragraph (1), the provisions of this subchapter shall apply*
 22 *to any affected agency beginning on a date set by the Presi-*
 23 *dent. Such date may be no later than 6 months after the*
 24 *date of such determination.*

25 **["(c)(1)** *This subchapter shall not apply to risk assess-*
 26 *ments or risk characterizations performed with respect to—*

1 【“(A) an emergency determined by the head of
2 an agency;

3 【“(B) a health, safety, or environmental inspec-
4 tion or individual facility permitting action; or

5 【“(C) a screening analysis.

6 【“(2) This subchapter shall not apply to any food,
7 drug, or other product label, or to any risk characterization
8 appearing on any such label.

9 **【“§634. Savings provisions**

10 【“Nothing in this subchapter shall be construed to—

11 【“(1) modify any statutory standard or require-
12 ment designed to protect human health, safety, or the
13 environment;

14 【“(2) preclude the consideration of any data or
15 the calculation of any estimate to more fully describe
16 risk or provide examples of scientific uncertainty or
17 variability; or

18 【“(3) require the disclosure of any trade secret
19 or other confidential information.

20 **【“§635. Principles for risk assessment**

21 【“(a) The head of each covered agency shall ensure
22 that risk assessments and all of the components of such as-
23 sessments—

24 【“(1) provide for a systematic means to struc-
25 ture information useful to decision makers;

1 【“(2) provide, to the maximum extent prac-
 2 ticable, that policy-driven default assumptions be used
 3 only in the absence of relevant available information;

4 【“(3) promote involvement from all stakeholders;

5 【“(4) provide an opportunity for public input
 6 throughout the regulatory process; and

7 【“(5) are designed so that the degree of specific-
 8 ity and rigor employed is commensurate with the con-
 9 sequences of the decision to be made.

10 【“(b) A risk assessment shall, to the maximum extent
 11 practicable, clearly delineate hazard identification from
 12 dose-response and exposure assessment and make clear the
 13 relationship between the level of risk and the level of expo-
 14 sure to a hazard.

15 **【“§636. Principles for risk characterization**

16 【“In characterizing risk in any risk assessment docu-
 17 ment, regulatory proposal, or decision, each covered agency
 18 shall include in the risk characterization, as appropriate,
 19 each of the following:

20 【“(1)(A) A description of the exposure scenarios
 21 used, the natural resources or subpopulations being
 22 exposed, and the likelihood of those exposure scenarios.

23 【“(B) When a risk assessment involves a choice
 24 of any significant assumption, inference, or model,

1 *the covered agency or instrumentality preparing the*
 2 *risk assessment shall—*

3 **【**“(i) *identify the assumptions, inferences,*
 4 *and models that materially affect the outcome;*

5 **【**“(ii) *explain the basis for any choices;*

6 **【**“(iii) *identify any policy decisions or pol-*
 7 *icy-based default assumptions;*

8 **【**“(iv) *indicate the extent to which any sig-*
 9 *nificant model has been validated by, or conflicts*
 10 *with, empirical data; and*

11 **【**“(v) *describe the impact of alternative*
 12 *choices of assumptions, default options or mathe-*
 13 *matical models.*

14 **【**“(C) *The major sources of uncertainties in the*
 15 *hazard identification, dose-response and exposure as-*
 16 *essment phases of the risk assessment.*

17 **【**“(D) *To the extent feasible, the range and dis-*
 18 *tribution of exposures and risks derived from the risk*
 19 *assessment should be included as a component of the*
 20 *risk characterization.*

21 **【**“(2) *When a covered agency provides a risk as-*
 22 *essment or risk characterization for a proposed or*
 23 *final regulatory action, such assessment or character-*
 24 *ization shall include a statement of any significant*

1 *substitution risks, when information on such risks has*
 2 *been made available to the agency.*

3 **【“§637. Peer review**

4 **【“(a) The head of each covered agency shall develop**
 5 *a systematic program for independent and external peer re-*
 6 *view required under subsection (b). Such program shall be*
 7 *applicable throughout each covered agency and—*

8 **【“(1) shall provide for the creation of peer re-**
 9 *view panels that—*

10 **【“(A) consist of members with expertise rel-**
 11 *evant to the sciences involved in regulatory deci-*
 12 *sions and who are independent of the covered*
 13 *agency; and*

14 **【“(B) are broadly representative and bal-**
 15 *anced and, to the extent relevant and appro-*
 16 *priate, may include persons affiliated with Fed-*
 17 *eral, State, local, or tribal governments, small*
 18 *businesses, other representatives of industry, uni-*
 19 *versities, agriculture, labor consumers, conserva-*
 20 *tion organizations, or other public interest*
 21 *groups and organizations;*

22 **【“(2) shall not exclude any person with substan-**
 23 *tial and relevant expertise as a panel member on the*
 24 *basis that such person represents an entity that may*
 25 *have a potential interest in the outcome, if such inter-*

1 *est is fully disclosed to the agency, and in the case of*
2 *a regulatory decision affecting a single entity, no peer*
3 *reviewer representing such entity may be included on*
4 *the panel;*

5 **■**“(3) *shall provide for a timely completed peer*
6 *review, meeting agency deadlines, that contains a bal-*
7 *anced presentation of all considerations, including*
8 *minority reports and an agency response to all sig-*
9 *nificant peer review comments; and*

10 **■**“(4) *shall provide adequate protections for con-*
11 *fidential business information and trade secrets, in-*
12 *cluding requiring panel members to enter into con-*
13 *fidentiality agreements.*

14 **■**“(b)(1)(A) *Except as provided under subparagraph*
15 *(B), each covered agency shall provide for peer review in*
16 *accordance with this section of any risk assessment or cost-*
17 *benefit analysis that forms the basis of any major rule that*
18 *addresses risks to the environment, health, or safety.*

19 **■**“(B) *Subparagraph (A) shall not apply to a rule or*
20 *other action taken by an agency to authorize or approve*
21 *any individual substance or product.*

22 **■**“(2) *The Director of the Office of Management and*
23 *Budget may order that peer review be provided for any risk*
24 *assessment or cost-benefit analysis that is likely to have a*

1 *significant impact on public policy decisions or would es-*
 2 *tablish an important precedent.*

3 **¶**“(c) *Each peer review under this section shall include*
 4 *a report to the Federal agency concerned with respect to*
 5 *the scientific and technical merit of data and methods used*
 6 *for the risk assessments or cost-benefit analyses.*

7 **¶**“(d) *The head of the covered agency shall provide a*
 8 *written response to all significant peer review comments.*

9 **¶**“(e) *All peer review comments or conclusions and the*
 10 *agency’s responses shall be made available to the public and*
 11 *shall be made part of the administrative record for purposes*
 12 *of judicial review of any final agency action.*

13 **¶**“(f) *No peer review shall be required under this sec-*
 14 *tion for any data, method, document, or assessment, or any*
 15 *component thereof, which has been previously subjected to*
 16 *peer review.*

17 **¶“§638. Guidelines, plan for assessing new informa-**
 18 **tion, and report**

19 **¶**“(a)(1)(A) *As soon as practicable and scientifically*
 20 *feasible, each covered agency shall adopt, after notification*
 21 *and opportunity for public comment, guidelines to imple-*
 22 *ment the risk assessment and risk characterization prin-*
 23 *ciples under sections 635 and 636, as well as the cost-benefit*
 24 *analysis requirements under section 622, and shall provide*
 25 *a format for summarizing risk assessment results.*

1 **¶**“(B) No later than 12 months after the effective date
 2 of this section, the head of each covered agency shall issue
 3 a report on the status of such guidelines to the Congress.

4 **¶**“(2) The guidelines under paragraph (1) shall—

5 **¶**“(A) include guidance on use of specific tech-
 6 nical methodologies and standards for acceptable
 7 quality of specific kinds of data;

8 **¶**“(B) address important decisional factors for
 9 the risk assessment, risk characterization, and cost-
 10 benefit analysis at issue; and

11 **¶**“(C) provide procedures for the refinement and
 12 replacement of policy-based default assumptions.

13 **¶**“(b) The guidelines, plan and report under this sec-
 14 tion shall be developed after notice and opportunity for pub-
 15 lic comment, and after consultation with representatives of
 16 appropriate State agencies and local governments, and such
 17 other departments and agencies, organizations, or persons
 18 as may be advisable.

19 **¶**“(c) The President shall review the guidelines pub-
 20 lished under this section at least every 4 years.

21 **¶**“(d) The development, issuance, and publication of
 22 risk assessment and risk characterization guidelines under
 23 this section shall not be subject to judicial review.

1 **["§ 639. Research and training in risk assessment**

2 **["(a) The head of each covered agency shall regularly**
3 **and systematically evaluate risk assessment research and**
4 **training needs of the agency, including, where relevant and**
5 **appropriate, the following:**

6 **["(1) Research to reduce generic data gaps, to**
7 **address modelling needs (including improved model**
8 **sensitivity), and to validate default options, particu-**
9 **larly those common to multiple risk assessments.**

10 **["(2) Research leading to improvement of meth-**
11 **ods to quantify and communicate uncertainty and**
12 **variability among individuals, species, populations,**
13 **and, in the case of ecological risk assessment, ecologi-**
14 **cal communities.**

15 **["(3) Emerging and future areas of research, in-**
16 **cluding research on comparative risk analysis, expo-**
17 **sure to multiple chemicals and other stressors,**
18 **noncancer endpoints, biological markers of exposure**
19 **and effect, mechanisms of action in both mammalian**
20 **and nonmammalian species, dynamics and prob-**
21 **abilities of physiological and ecosystem exposures, and**
22 **prediction of ecosystem-level responses.**

23 **["(4) Long-term needs to adequately train indi-**
24 **viduals in risk assessment and risk assessment appli-**
25 **cation. Evaluations under this paragraph shall in-**

1 *clude an estimate of the resources needed to provide*
 2 *necessary training.*

3 **¶**“(b) *The head of each covered agency shall develop*
 4 *a strategy and schedule for carrying out research and train-*
 5 *ing to meet the needs identified in subsection (a).*

6 **¶“§640. Interagency coordination**

7 **¶**“(a) *To promote the conduct, application, and prac-*
 8 *tice of risk assessment in a consistent manner and to iden-*
 9 *tify risk assessment data and research needs common to*
 10 *more than 1 Federal agency, the Director of the Office of*
 11 *Management and Budget, in consultation with the Office*
 12 *of Science and Technology Policy, shall—*

13 **¶**“(1) *periodically survey the manner in which*
 14 *each Federal agency involved in risk assessment is*
 15 *conducting such risk assessment to determine the*
 16 *scope and adequacy of risk assessment practices in*
 17 *use by the Federal Government;*

18 **¶**“(2) *provide advice and recommendations to*
 19 *the President and Congress based on the surveys con-*
 20 *ducted and determinations made under paragraph*
 21 *(1);*

22 **¶**“(3) *establish appropriate interagency mecha-*
 23 *nisms to promote—*

24 **¶**“(A) *coordination among Federal agencies*
 25 *conducting risk assessment with respect to the*

1 *conduct, application, and practice of risk assess-*
 2 *ment; and*

3 **【“(B) the use of state-of-the-art risk assess-**
 4 *ment practices throughout the Federal Govern-*
 5 *ment;*

6 **【“(4) establish appropriate mechanisms between**
 7 *Federal and State agencies to communicate state-of-*
 8 *the-art risk assessment practices; and*

9 **【“(5) periodically convene meetings with State**
 10 *government representatives and Federal and other*
 11 *leaders to assess the effectiveness of Federal and State*
 12 *cooperation in the development and application of*
 13 *risk assessment.*

14 **【“(b) The President shall appoint National Peer Re-**
 15 *view Panels to review every 3 years the risk assessment*
 16 *practices of each covered agency for programs designed to*
 17 *protect human health, safety, or the environment. The Pan-*
 18 *els shall submit a report to the President and the Congress*
 19 *at least every 3 years containing the results of such review.*

20 **【“§640a. Plan for review of risk assessments**

21 **【“(a) No later than 18 months after the effective date**
 22 *of this section, the head of each covered agency shall publish*
 23 *a plan to review and revise any risk assessment published*
 24 *before the expiration of such 18-month period if the covered*
 25 *agency determines that significant new information or*

1 methodologies are available that could significantly alter
 2 the results of the prior risk assessment.

3 **【“(b) A plan under subsection (a) shall—**

4 **【“(1) provide procedures for receiving and con-**
 5 **sidering new information and risk assessments from**
 6 **the public; and**

7 **【“(2) set priorities and criteria for review and**
 8 **revision of risk assessments based on such factors as**
 9 **the agency head considers appropriate.**

10 **【“§ 640b. Judicial review**

11 **【“The provisions of section 623 relating to judicial re-**
 12 **view shall apply to this subchapter.**

13 **【“§ 640c. Deadlines for rulemaking**

14 **【“The provisions of section 624 relating to deadlines**
 15 **for rulemaking shall apply to this subchapter.**

16 **【“SUBCHAPTER IV—EXECUTIVE OVERSIGHT**

17 **【“§ 641. Definition**

18 **【“For purposes of this subchapter, the definitions**
 19 **under sections 551 and 621 shall apply.**

20 **【“§ 642. Procedures**

21 **【“The Director or other designated officer to whom au-**
 22 **thority is delegated under section 644 shall—**

23 **【“(1) establish procedures for agency compliance**
 24 **with this chapter; and**

1 **¶**“(2) monitor, review, and ensure agency imple-
 2 mentation of such procedures.

3 **¶“§643. Promulgation and adoption**

4 **¶**“(a) Procedures established pursuant to section 642
 5 shall only be implemented after opportunity for public com-
 6 ment. Any such procedures shall be consistent with the
 7 prompt completion of rulemaking proceedings.

8 **¶**“(b)(1) If procedures established pursuant to section
 9 642 include review of any initial or final analyses of a rule
 10 required under this chapter, the time for any such review
 11 of any initial analysis shall not exceed 60 days following
 12 the receipt of the analysis by the Director, a designee of
 13 the President, or by an officer to whom the authority grant-
 14 ed under section 642 has been delegated pursuant to section
 15 644.

16 **¶**“(2) The time for review of any final analysis re-
 17 quired under this chapter shall not exceed 60 days following
 18 the receipt of the analysis by the Director, a designee of
 19 the President, or such officer.

20 **¶**“(3)(A) The times for each such review may be ex-
 21 tended for good cause by the President or such officer for
 22 an additional 30 days.

23 **¶**“(B) Notice of any such extension, together with a
 24 succinct statement of the reasons therefor, shall be inserted
 25 in the rulemaking file.

1 **["§644. Delegation of authority**

2 **["***“(a) The President shall delegate the authority grant-*
 3 *ed by this subchapter to the Director or to another officer*
 4 *within the Executive Office of the President whose appoint-*
 5 *ment has been subject to the advice and consent of the Sen-*
 6 *ate.*

7 **["***“(b) Notice of any delegation, or any revocation or*
 8 *modification thereof shall be published in the Federal Reg-*
 9 *ister.*

10 **["§645. Public disclosure of information**

11 **["***“The Director or other designated officer to whom au-*
 12 *thority is delegated under section 644, in carrying out the*
 13 *provisions of section 642, shall establish procedures (cover-*
 14 *ing all employees of the Director or other designated officer)*
 15 *to provide public and agency access to information concern-*
 16 *ing regulatory review actions, including—*

17 **["***“(1) disclosure to the public on an ongoing*
 18 *basis of information regarding the status of regu-*
 19 *latory actions undergoing review;*

20 **["***“(2) disclosure to the public, no later than pub-*
 21 *lication of, or other substantive notice to the public*
 22 *concerning a regulatory action, of—*

23 **["***“(A) all written communications, regard-*
 24 *less of form or format, including drafts of all*
 25 *proposals and associated analyses, between the*

1 *Director or other designated officer and the regu-*
2 *latory agency;*

3 **【“(B) all written communications, regard-**
4 *less of form or format, between the Director or*
5 *other designated officer and any person not em-*
6 *ployed by the executive branch of the Federal*
7 *Government relating to the substance of a regu-*
8 *latory action;*

9 **【“(C) a record of all oral communications**
10 *relating to the substance of a regulatory action*
11 *between the Director or other designated officer*
12 *and any person not employed by the executive*
13 *branch of the Federal Government; and*

14 **【“(D) a written explanation of any review**
15 *action and the date of such action; and*

16 **【“(3) disclosure to the regulatory agency, on a**
17 *timely basis, of—*

18 **【“(A) all written communications between**
19 *the Director or other designated officer and any*
20 *person who is not employed by the executive*
21 *branch of the Federal Government;*

22 **【“(B) a record of all oral communications,**
23 *and an invitation to participate in meetings, re-*
24 *lating to the substance of a regulatory action be-*
25 *tween the Director or other designated officer*

1 *and any person not employed by the executive*
 2 *branch of the Federal Government; and*

3 **[(C)** *a written explanation of any review*
 4 *action taken concerning an agency regulatory*
 5 *action.*

6 **["§646. Judicial review**

7 **[(***"The exercise of the authority granted under this sub-*
 8 *chapter by the Director, the President, or by an officer to*
 9 *whom such authority has been delegated under section 644*
 10 *shall not be subject to judicial review in any manner."***)]**

11 **[(b) REGULATORY FLEXIBILITY ANALYSIS.—**

12 **[(1) IN GENERAL.—***Section 611 of title 5,*
 13 *United States Code, is amended to read as follows:*

14 **["§611. Judicial review**

15 **[(***"(a)(1) Except as provided in paragraph (2), no*
 16 *later than 1 year after the effective date of a final rule with*
 17 *respect to which an agency—*

18 **[(***"(A) certified, pursuant to section 605(b), that*
 19 *such rule would not have a significant economic im-*
 20 *pact on a substantial number of small entities; or*

21 **[(***"(B) prepared a final regulatory flexibility*
 22 *analysis pursuant to section 604,*

23 *an affected small entity may petition for the judicial review*
 24 *of such certification or analysis in accordance with this*
 25 *subsection. A court having jurisdiction to review such rule*

1 *for compliance with section 553 of this title or under any*
 2 *other provision of law shall have jurisdiction to review such*
 3 *certification or analysis.*

4 **¶**“(2)(A) *Except as provided in subparagraph (B), in*
 5 *the case of a provision of law that requires that an action*
 6 *challenging a final agency regulation be commenced before*
 7 *the expiration of the 1-year period provided in paragraph*
 8 *(1), such lesser period shall apply to a petition for the judi-*
 9 *cial review under this subsection.*

10 **¶**“(B) *In a case in which an agency delays the issu-*
 11 *ance of a final regulatory flexibility analysis pursuant to*
 12 *section 608(b), a petition for judicial review under this sub-*
 13 *section shall be filed no later than—*

14 **¶**“(i) *1 year; or*

15 **¶**“(ii) *in a case in which a provision of law re-*
 16 *quires that an action challenging a final agency regu-*
 17 *lation be commenced before the expiration of the 1-*
 18 *year period provided in paragraph (1), the number of*
 19 *days specified in such provision of law,*
 20 *after the date the analysis is made available to the public.*

21 **¶**“(3) *For purposes of this subsection, the term ‘af-*
 22 *ected small entity’ means a small entity that is or will*
 23 *be adversely affected by the final rule.*

24 **¶**“(4) *Nothing in this subsection shall be construed to*
 25 *affect the authority of any court to stay the effective date*

1 *of any rule or provision thereof under any other provision*
2 *of law.*

3 **¶**“(5)(A) *In a case in which an agency certifies that*
4 *such rule would not have a significant economic impact on*
5 *a substantial number of small entities, the court may order*
6 *the agency to prepare a final regulatory flexibility analysis*
7 *pursuant to section 604 if the court determines, on the basis*
8 *of the rulemaking record, that the certification was arbi-*
9 *trary, capricious, an abuse of discretion, or otherwise not*
10 *in accordance with law.*

11 **¶**“(B) *In a case in which the agency prepared a final*
12 *regulatory flexibility analysis, the court may order the*
13 *agency to take corrective action consistent with section 604*
14 *if the court determines, on the basis of the rulemaking*
15 *record, that the final regulatory flexibility analysis was*
16 *prepared by the agency without complying with section 604.*

17 **¶**“(6) *If, by the end of the 90-day period beginning*
18 *on the date of the order of the court pursuant to paragraph*
19 *(5) (or such longer period as the court may provide), the*
20 *agency fails, as appropriate—*

21 **¶**“(A) *to prepare the analysis required by sec-*
22 *tion 604; or*

23 **¶**“(B) *to take corrective action consistent with*
24 *section 604 of this title,*

1 *the court may stay the rule or grant such other relief as*
 2 *it deems appropriate.*

3 **¶**“(7) *In making any determination or granting any*
 4 *relief authorized by this subsection, the court shall take due*
 5 *account of the rule of prejudicial error.*

6 **¶**“(b) *In an action for the judicial review of a rule,*
 7 *any regulatory flexibility analysis for such rule (including*
 8 *an analysis prepared or corrected pursuant to subsection*
 9 *(a)(5)) shall constitute part of the whole record of agency*
 10 *action in connection with such review.*

11 **¶**“(c) *Nothing in this section bars judicial review of*
 12 *any other impact statement or similar analysis required*
 13 *by any other law if judicial review of such statement or*
 14 *analysis is otherwise provided by law.”.*

15 **¶**(2) *EFFECTIVE DATE.— The amendment made*
 16 *by paragraph (1) shall take effect on the effective date*
 17 *of this Act, except that the judicial review authorized*
 18 *by section 611(a) of title 5, United States Code (as*
 19 *added by subsection (a)), shall apply only to final*
 20 *agency rules issued after such effective date.*

21 **¶**(c) *PRESIDENTIAL AUTHORITY.— Nothing in this*
 22 *Act shall limit the exercise by the President of the authority*
 23 *and responsibility that the President otherwise possesses*
 24 *under the Constitution and other laws of the United States*

1 *with respect to regulatory policies, procedures, and pro-*
 2 *grams of departments, agencies, and offices.*

3 **[(d) TECHNICAL AND CONFORMING AMENDMENTS.—**

4 **[(1) Part I of title 5, United States Code, is**
 5 *amended by striking out the chapter heading and*
 6 *table of sections for chapter 6 and inserting in lieu*
 7 *thereof the following:*

8 **["CHAPTER 6—THE ANALYSIS OF**
 9 **REGULATORY FUNCTIONS**

["SUBCHAPTER I—REGULATORY ANALYSIS

["Sec.

["601. Definitions.

["602. Regulatory agenda.

["603. Initial regulatory flexibility analysis.

["604. Final regulatory flexibility analysis.

["605. Avoidance of duplicative or unnecessary analyses.

["606. Effect on other law.

["607. Preparation of analysis.

["608. Procedure for waiver or delay of completion.

["609. Procedures for gathering comments.

["610. Periodic review of rules.

["611. Judicial review.

["612. Reports and intervention rights.

["SUBCHAPTER II—ANALYSIS OF AGENCY RULES

["621. Definitions.

["622. Rulemaking cost-benefit analysis.

["623. Judicial review.

["624. Deadlines for rulemaking.

["625. Agency review of rules.

["626. Public participation and accountability.

["SUBCHAPTER III—RISK ASSESSMENTS

["631. Findings and purposes.

["632. Definitions.

["633. Applicability.

["634. Savings provisions.

["635. Principles for risk assessment.

["636. Principles for risk characterization.

["637. Peer review.

["638. Guidelines, plan for assessing new information, and report.

["639. Research and training in risk assessment.

- 【“640. Interagency coordination.
- 【“640a. Plan for review of risk assessments.
- 【“640b. Judicial review.
- 【“640c. Deadlines for rulemaking.

【“SUBCHAPTER IV—EXECUTIVE OVERSIGHT

- 【“641. Definition.
- 【“642. Procedures.
- 【“643. Promulgation and adoption.
- 【“644. Delegation of authority.
- 【“645. Public disclosure of information.
- 【“646. Judicial review.”.

1 【(2) Chapter 6 of title 5, United States Code, is
2 amended by inserting immediately before section 601,
3 the following subchapter heading:

4 【“SUBCHAPTER I—REGULATORY ANALYSIS”.

5 **【SEC. 4. CONGRESSIONAL REVIEW.**

6 【(a) *IN GENERAL.*—Part I of title 5, United States
7 Code, is amended by inserting after chapter 7 the following
8 new chapter:

9 **【“CHAPTER 8—CONGRESSIONAL REVIEW**
10 **OF AGENCY RULEMAKING**

11 **【“§ 801. Congressional review of agency rulemaking**

12 【“(a) For purposes of this chapter, the term—

13 【“(1) ‘major rule’ means a major rule as defined
14 under section 621(4) of this title and as determined
15 under section 622 of this title; and

16 【“(2) ‘rule’ (except in reference to a rule of the
17 Senate or House of Representatives) is a reference to
18 a major rule.

1 **¶**“(b)(1) Upon the promulgation of a final major rule,
 2 the agency promulgating such rule shall submit to the Con-
 3 gress a copy of the rule, the statement of basis and purpose
 4 for the rule, and the proposed effective date of the rule.

5 **¶**“(2) A rule submitted under paragraph (1) shall not
 6 take effect as a final rule before the latest of the following:

7 **¶**“(A) The later of the date occurring 45 days
 8 after the date on which—

9 **¶**“(i) the Congress receives the rule submit-
 10 ted under paragraph (1); or

11 **¶**“(ii) the rule is published in the Federal
 12 Register.

13 **¶**“(B) If the Congress passes a joint resolution of
 14 disapproval described under subsection (i) relating to
 15 the rule, and the President signs a veto of such resolu-
 16 tion, the earlier date—

17 **¶**“(i) on which either House of Congress
 18 votes and fails to override the veto of the Presi-
 19 dent; or

20 **¶**“(ii) occurring 30 session days after the
 21 date on which the Congress received the veto and
 22 objections of the President.

23 **¶**“(C) The date the rule would have otherwise
 24 taken effect, if not for this section (unless a joint reso-

1 *lution of disapproval under subsection (i) is ap-*
 2 *proved).*

3 **¶**“(c) *A major rule shall not take effect as a final rule*
 4 *if the Congress passes a joint resolution of disapproval de-*
 5 *scribed under subsection (i), which is signed by the Presi-*
 6 *dent or is vetoed and overridden by the Congress.*

7 **¶**“(d)(1) *Notwithstanding any other provision of this*
 8 *section (except subject to paragraph (2)), a major rule that*
 9 *would not take effect by reason of this section may take ef-*
 10 *fect if the President makes a determination and submits*
 11 *written notice of such determination to the Congress that*
 12 *the major rule should take effect because such major rule*
 13 *is—*

14 **¶**“(A) *necessary because of an imminent threat*
 15 *to health or safety, or other emergency;*

16 **¶**“(B) *necessary for the enforcement of criminal*
 17 *laws; or*

18 **¶**“(C) *necessary for national security.*

19 **¶**“(2) *An exercise by the President of the authority*
 20 *under this subsection shall have no effect on the procedures*
 21 *under subsection (i) or the effect of a joint resolution of dis-*
 22 *approval under this section.*

23 **¶**“(e)(1) *Subsection (i) shall apply to any major rule*
 24 *that is promulgated as a final rule during the period begin-*
 25 *ning on the date occurring 60 days before the date the Con-*

1 *gress adjourns sine die through the date on which the suc-*
2 *ceeding Congress first convenes.*

3 **¶**“(2) *For purposes of subsection (i), a major rule de-*
4 *scribed under paragraph (1) shall be treated as though such*
5 *rule were published in the Federal Register (as a rule that*
6 *shall take effect as a final rule) on the date the succeeding*
7 *Congress first convenes.*

8 **¶**“(3) *During the period between the date the Congress*
9 *adjourns sine die through the date on which the succeeding*
10 *Congress first convenes, a rule described under paragraph*
11 *(1) shall take effect as a final rule as otherwise provided*
12 *by law.*

13 **¶**“(f) *Any rule that takes effect and later is made of*
14 *no force or effect by the enactment of a joint resolution*
15 *under subsection (i) shall be treated as though such rule*
16 *had never taken effect.*

17 **¶**“(g) *If the Congress does not enact a joint resolution*
18 *of disapproval under subsection (i), no court or agency may*
19 *infer any intent of the Congress from any action or inaction*
20 *of the Congress with regard to such major rule, related stat-*
21 *ute, or joint resolution of disapproval.*

22 **¶**“(h) *If the agency fails to comply with the require-*
23 *ments of subsection (b) for any rule, the rule shall cease*
24 *to be enforceable against any person.*

1 **¶**“(i)(1) For purposes of this subsection, the term ‘joint
 2 resolution’ means only a joint resolution introduced after
 3 the date on which the rule referred to in subsection (b) is
 4 received by Congress the matter after the resolving clause
 5 of which is as follows: ‘That Congress disapproves the rule
 6 submitted by the _____ relating to
 7 _____, and such rule shall have no force or ef-
 8 fect.’ (The blank spaces being appropriately filled in.)

9 **¶**“(2)(A) In the Senate, a resolution described in para-
 10 graph (1) shall be referred to the committees with jurisdic-
 11 tion. Such a resolution shall not be reported before the
 12 eighth day after its submission or publication date.

13 **¶**“(B) For purposes of this subsection, the term ‘sub-
 14 mission or publication date’ means the later of the date on
 15 which—

16 **¶**“(i) the Congress receives the rule submitted
 17 under subsection (b)(1); or

18 **¶**“(ii) the rule is published in the Federal Reg-
 19 ister.

20 **¶**“(3) In the Senate, if the committee to which a reso-
 21 lution described in paragraph (1) is referred has not re-
 22 ported such resolution (or an identical resolution) at the
 23 end of 20 calendar days after its submission or publication
 24 date, such committee may be discharged on a petition ap-
 25 proved by 30 Senators from further consideration of such

1 *resolution and such resolution shall be placed on the Senate*
2 *calendar.*

3 **¶**“(4)(A) *In the Senate, when the committee to which*
4 *a resolution is referred has reported, or when a committee*
5 *is discharged (under paragraph (3)) from further consider-*
6 *ation of, a resolution described in paragraph (1), it shall*
7 *at any time thereafter be in order (even though a previous*
8 *motion to the same effect has been disagreed to) for any*
9 *Senator to move to proceed to the consideration of the reso-*
10 *lution, and all points of order against the resolution (and*
11 *against consideration of the resolution) shall be waived. The*
12 *motion shall be privileged in the Senate and shall not be*
13 *debatable. The motion shall not be subject to amendment,*
14 *or to a motion to postpone, or to a motion to proceed to*
15 *the consideration of other business. A motion to reconsider*
16 *the vote by which the motion is agreed to or disagreed to*
17 *shall not be in order. If a motion to proceed to the consider-*
18 *ation of the resolution is agreed to, the resolution shall re-*
19 *main the unfinished business of the Senate until disposed*
20 *of.*

21 **¶**“(B) *In the Senate, debate on the resolution, and on*
22 *all debatable motions and appeals in connection therewith,*
23 *shall be limited to not more than 10 hours, which shall be*
24 *divided equally between those favoring and those opposing*
25 *the resolution. A motion further to limit debate shall be in*

1 *order and shall not be debatable. An amendment to, or a*
 2 *motion to postpone, or a motion to proceed to the consider-*
 3 *ation of other business, or a motion to recommit the resolu-*
 4 *tion shall not be in order. A motion to reconsider the vote*
 5 *by which the resolution is agreed to or disagreed to shall*
 6 *not be in order.*

7 **¶**“(C) *In the Senate, immediately following the conclu-*
 8 *sion of the debate on a resolution described in paragraph*
 9 *(1), and a single quorum call at the conclusion of the debate*
 10 *if requested in accordance with the Senate rules, the vote*
 11 *on final passage of the resolution shall occur.*

12 **¶**“(D) *Appeals from the decisions of the Chair relating*
 13 *to the application of the rules of the Senate to the procedure*
 14 *relating to a resolution described in paragraph (1) shall*
 15 *be decided without debate.*

16 **¶**“(5) *If, before the passage in the Senate of a resolu-*
 17 *tion described in paragraph (1), the Senate receives from*
 18 *the House of Representatives a resolution described in para-*
 19 *graph (1), then the following procedures shall apply:*

20 **¶**“(A) *The resolution of the House of Representa-*
 21 *tives shall not be referred to a committee.*

22 **¶**“(B) *With respect to a resolution described in*
 23 *paragraph (1) of the Senate—*

1 **[(i)** *the procedure in the Senate shall be*
 2 *the same as if no resolution had been received*
 3 *from the other House; but*

4 **[(ii)** *the vote on final passage shall be on*
 5 *the resolution of the other House.*

6 **[(6)** *This subsection is enacted by Congress—*

7 **[(A)** *as an exercise of the rulemaking power of*
 8 *the Senate and House of Representatives, respectively,*
 9 *and as such it is deemed to be a part of the rules of*
 10 *each House, respectively, but applicable only with re-*
 11 *spect to the procedure to be followed in that House in*
 12 *the case of a resolution described in paragraph (1),*
 13 *and it supersedes other rules only to the extent that*
 14 *it is inconsistent with such rules; and*

15 **[(B)** *with full recognition of the constitutional*
 16 *right of either House to change the rules (so far as re-*
 17 *lating to the procedure of that House) at any time,*
 18 *in the same manner, and to the same extent as in the*
 19 *case of any other rule of that House.*

20 **[(j)** *No requirements under this chapter shall be sub-*
 21 *ject to judicial review in any manner.”.*

22 **[(b)** *TECHNICAL AND CONFORMING AMENDMENT.—*
 23 *The table of chapters for part I of title 5, United States*
 24 *Code, is amended by inserting after the item relating to*
 25 *chapter 7 the following:*

“8. Congressional Review of Agency Rulemaking 801”.

1 **[SEC. 5. STUDIES AND REPORTS.]**

2 **[(a) RISK ASSESSMENTS.]**—*The Administrative Con-*
 3 *ference of the United States shall—*

4 **[(1)]** *develop and carry out an ongoing study of*
 5 *the operation of the risk assessment requirements of*
 6 *subchapter III of chapter 6 of title 5, United States*
 7 *Code (as added by section 3 of this Act); and*

8 **[(2)]** *submit an annual report to the Congress on*
 9 *the findings of the study.*

10 **[(b) ADMINISTRATIVE PROCEDURE ACT.]**—*No later*
 11 *than December 31, 1996, the Administrative Conference of*
 12 *the United States shall—*

13 **[(1)]** *carry out a study of the operation of chap-*
 14 *ters 5 and 6 of title 5, United States Code (commonly*
 15 *referred to as the Administrative Procedure Act), as*
 16 *amended by section 3 of this Act; and*

17 **[(2)]** *submit a report to the Congress on the find-*
 18 *ings of the study, including proposals for revision, if*
 19 *any.*

20 **[SEC. 6. RISK-BASED PRIORITIES.]**

21 **[(a) PURPOSES.]**—*The purposes of this section are*
 22 *to—*

23 **[(1)]** *encourage Federal agencies engaged in reg-*
 24 *ulating risks to human health, safety, and the envi-*
 25 *ronment to achieve the greatest risk reduction at the*
 26 *least cost practical;*

1 **[(2)** *promote the coordination of policies and*
 2 *programs to reduce risks to human health, safety, and*
 3 *the environment; and*

4 **[(3)** *promote open communication among Fed-*
 5 *eral agencies, the public, the President, and Congress*
 6 *regarding environmental, health, and safety risks,*
 7 *and the prevention and management of those risks.*

8 **[(b)** *DEFINITIONS.—For the purposes of this section:*

9 **[(1)** *COMPARATIVE RISK ANALYSIS.—The term*
 10 *“comparative risk analysis” means a process to sys-*
 11 *tematically estimate, compare, and rank the size and*
 12 *severity of risks to provide a common basis for evalu-*
 13 *ating strategies for reducing or preventing those risks.*

14 **[(2)** *COVERED AGENCY.—The term “covered*
 15 *agency” means each of the following:*

16 **[(A)** *The Environmental Protection Agen-*
 17 *cy.*

18 **[(B)** *The Department of Labor.*

19 **[(C)** *The Department of Transportation.*

20 **[(D)** *The Food and Drug Administration.*

21 **[(E)** *The Department of Energy.*

22 **[(F)** *The Department of the Interior.*

23 **[(G)** *The Department of Agriculture.*

24 **[(H)** *The Consumer Product Safety Com-*
 25 *mission.*

1 **[(I)** *The National Oceanic and Atmos-*
 2 *pheric Administration.*

3 **[(J)** *The United States Army Corps of En-*
 4 *gineers.*

5 **[(K)** *The Nuclear Regulatory Commission.*

6 **[(3)** *EFFECT.*—*The term “effect” means a delete-*
 7 *rious change in the condition of—*

8 **[(A)** *a human or other living thing (includ-*
 9 *ing death, cancer, or other chronic illness, de-*
 10 *creased reproductive capacity, or disfigurement);*
 11 *or*

12 **[(B)** *an inanimate thing important to*
 13 *human welfare (including destruction, degenera-*
 14 *tion, the loss of intended function, and increased*
 15 *costs for maintenance).*

16 **[(4)** *IRREVERSIBILITY.*—*The term “irre-*
 17 *versibility” means the extent to which a return to*
 18 *conditions before the occurrence of an effect are either*
 19 *very slow or will never occur.*

20 **[(5)** *LIKELIHOOD.*—*The term “likelihood”*
 21 *means the estimated probability that an effect will*
 22 *occur.*

23 **[(6)** *MAGNITUDE.*—*The term “magnitude”*
 24 *means the number of individuals or the quantity of*
 25 *ecological resources or other resources that contribute*

1 to human welfare that are affected by exposure to a
2 stressor.

3 **[(7) SERIOUSNESS.**—The term “seriousness”
4 means the intensity of effect, the likelihood, the
5 irreversibility, and the magnitude.

6 **[(c) DEPARTMENT AND AGENCY PROGRAM GOALS.**—

7 **[(1) SETTING PRIORITIES.**—In exercising au-
8 thority under applicable laws protecting human
9 health, safety, or the environment, the head of each
10 covered agency should set priorities and use the re-
11 sources available under those laws to address those
12 risks to human health, safety, and the environment
13 that—

14 **[(A)** the covered agency determines to be
15 the most serious; and

16 **[(B)** can be addressed in a cost-effective
17 manner, with the goal of achieving the greatest
18 overall net reduction in risks with the public and
19 private sector resources expended.

20 **[(2) DETERMINING THE MOST SERIOUS**
21 **RISKS.**—In identifying the greatest risks under para-
22 graph (1) of this subsection, each covered agency shall
23 consider, at a minimum—

24 **[(A)** the likelihood, irreversibility, and se-
25 verity of the effect; and

1 **[(B)** *the number and classes of individuals*
2 *potentially affected, and shall explicitly take into*
3 *account the results of the comparative risk anal-*
4 *ysis conducted under subsection (d) of this sec-*
5 *tion.*

6 **[(3) OMB REVIEW.—***The covered agency’s deter-*
7 *minations of the most serious risks for purposes of set-*
8 *ting priorities shall be reviewed and approved by the*
9 *Director of the Office of Management and Budget be-*
10 *fore submission of the covered agency’s annual budget*
11 *requests to Congress.*

12 **[(4) INCORPORATING RISK-BASED PRIORITIES**
13 **INTO BUDGET AND PLANNING.—***The head of each cov-*
14 *ered agency shall incorporate the priorities identified*
15 *under paragraph (1) into the agency budget, strategic*
16 *planning, regulatory agenda, enforcement, and re-*
17 *search activities. When submitting its budget request*
18 *to Congress and when announcing its regulatory*
19 *agenda in the Federal Register, each covered agency*
20 *shall identify the risks that the covered agency head*
21 *has determined are the most serious and can be ad-*
22 *dressed in a cost-effective manner under paragraph*
23 *(1), the basis for that determination, and explicitly*
24 *identify how the covered agency’s requested budget*
25 *and regulatory agenda reflect those priorities.*

1 **[(5) EFFECTIVE DATE.**—*This subsection shall*
 2 *take effect 12 months after the date of enactment of*
 3 *this Act.*

4 **[(d) COMPARATIVE RISK ANALYSIS.**—

5 **[(1) REQUIREMENT.**—(A)(i) *No later than 6*
 6 *months after the effective date of this Act, the Director*
 7 *of the Office of Management and Budget shall enter*
 8 *into appropriate arrangements with an accredited*
 9 *scientific body—*

10 **[(I)** *to conduct a study of the methodologies*
 11 *for using comparative risk to rank dissimilar*
 12 *human health, safety, and environmental risks;*
 13 *and*

14 **[(II)** *to conduct a comparative risk analy-*
 15 *sis.*

16 **[(ii)** *The comparative risk analysis shall com-*
 17 *pare and rank, to the extent feasible, human health,*
 18 *safety, and environmental risks potentially regulated*
 19 *across the spectrum of programs administered by all*
 20 *covered agencies.*

21 **[(B)** *The Director shall consult with the Office*
 22 *of Science and Technology Policy regarding the scope*
 23 *of the study and the conduct of the comparative risk*
 24 *analysis.*

1 **[(2) CRITERIA.**—*In arranging for the compara-*
2 *tive risk analysis referred to in paragraph (1) of this*
3 *subsection, the Director shall ensure that—*

4 **[(A)** *the scope and specificity of the analy-*
5 *sis are sufficient to provide the President and*
6 *agency heads guidance in allocating resources*
7 *across agencies and among programs in agencies*
8 *to achieve the greatest degree of risk prevention*
9 *and reduction for the public and private re-*
10 *sources expended;*

11 **[(B)** *the analysis is conducted through an*
12 *open process, by individuals with relevant exper-*
13 *tise, including toxicologists, biologists, engineers*
14 *and experts in medicine, industrial hygiene and*
15 *environmental effects;*

16 **[(C)** *the analysis is conducted, to the extent*
17 *feasible, consistent with the risk assessment and*
18 *risk characterization principles in sections 635*
19 *and 636 of this title;*

20 **[(D)** *the methodologies and principal sci-*
21 *entific determinations made in the analysis are*
22 *subjected to independent and external peer re-*
23 *view consistent with section 637, and the conclu-*
24 *sions of the peer review are made publicly avail-*

1 *able as part of the final report required under*
 2 *subsection (e);*

3 **[(E)** *there is an opportunity for public*
 4 *comment on the results before making them final;*
 5 *and*

6 **[(F)** *the results are presented in a manner*
 7 *that distinguishes between the scientific conclu-*
 8 *sions and any policy or value judgments em-*
 9 *bodied in the comparisons.*

10 **[(3) COMPLETION AND REVIEW.—***No later than*
 11 *3 years after the effective date of this Act, the com-*
 12 *parative risk analysis required under paragraph (1)*
 13 *shall be completed. The comparative risk analysis*
 14 *shall be reviewed and revised at least every 5 years*
 15 *thereafter for a minimum of 15 years following the*
 16 *release of the first analysis. The Director shall ar-*
 17 *range for such review and revision with an accredited*
 18 *scientific body in the same manner as provided under*
 19 *paragraphs (1) and (2).*

20 **[(4) STUDY.—***The study of methodologies pro-*
 21 *vided under paragraph (1) shall be conducted as part*
 22 *of the first comparative risk analysis and shall be*
 23 *completed no later than 180 days after the completion*
 24 *of that analysis. The goal of the study shall be to de-*
 25 *velop and rigorously test methods of comparative risk*

1 *analysis. The study shall have sufficient scope and*
 2 *breadth to test approaches for improving comparative*
 3 *risk analysis and its use in setting priorities for*
 4 *human health, safety, and environmental risk preven-*
 5 *tion and reduction.*

6 **[(5) TECHNICAL GUIDANCE.**—*No later than 180*
 7 *days after the effective date of this Act, the Director,*
 8 *in collaboration with other heads of covered agencies*
 9 *shall enter into a contract with the National Research*
 10 *Council to provide technical guidance to agencies on*
 11 *approaches to using comparative risk analysis in set-*
 12 *ting human health, safety, and environmental prior-*
 13 *ities to assist agencies in complying with subsection*
 14 *(c) of this section.*

15 **[(e) REPORTS AND RECOMMENDATIONS TO CONGRESS**
 16 *AND THE PRESIDENT.*—*No later than 24 months after the*
 17 *effective date of this Act, each covered agency shall submit*
 18 *a report to Congress and the President—*

19 **[(1)** *detailing how the agency has complied with*
 20 *subsection (c) and describing the reasons for any de-*
 21 *parture from the requirement to establish priorities to*
 22 *achieve the greatest overall net reduction in risk;*

23 **[(2)** *recommending—*

24 **[(A)** *modification, repeal, or enactment of*
 25 *laws to reform, eliminate, or enhance programs*

1 *or mandates relating to human health, safety, or*
 2 *the environment; and*

3 **[(B)** *modification or elimination of statu-*
 4 *torily or judicially mandated deadlines,*
 5 *that would assist the covered agency to set priorities*
 6 *in activities to address the risks to human health,*
 7 *safety, or the environment in a manner consistent*
 8 *with the requirements of subsection (c)(1);*

9 **[(3)** *evaluating the categories of policy and*
 10 *value judgments used in risk assessment, risk charac-*
 11 *terization, or cost-benefit analysis; and*

12 **[(4)** *discussing risk assessment research and*
 13 *training needs, and the agency's strategy and schedule*
 14 *for meeting those needs.*

15 **[(f)** *SAVINGS PROVISION AND JUDICIAL REVIEW.—*

16 **[(1)** *IN GENERAL.—Nothing in this section shall*
 17 *be construed to modify any statutory standard or re-*
 18 *quirement designed to protect human health, safety,*
 19 *or the environment.*

20 **[(2)** *JUDICIAL REVIEW.—Compliance or non-*
 21 *compliance by an agency with the provisions of this*
 22 *section shall not be subject to judicial review.*

23 **[(3)** *AGENCY ANALYSIS.—Any analysis prepared*
 24 *under this section shall not be subject to judicial con-*
 25 *sideration separate or apart from the requirement,*

1 *rule, program, or law to which it relates. When an*
 2 *action for judicial review of a covered agency action*
 3 *is instituted, any analysis for, or relating to, the ac-*
 4 *tion shall constitute part of the whole record of agency*
 5 *action for the purpose of judicial review of the action*
 6 *and shall, to the extent relevant, be considered by a*
 7 *court in determining the legality of the covered agen-*
 8 *cy action.*

9 **[SEC. 7. REGULATORY ACCOUNTING.]**

10 **[(a) DEFINITIONS.—***For purposes of this section, the*
 11 *following definitions apply:*

12 **[(1) AGENCY.—***The term “agency” means any*
 13 *executive department, military department, Govern-*
 14 *ment corporation, Government controlled corporation,*
 15 *or other establishment in the executive branch of the*
 16 *Government (including the Executive Office of the*
 17 *President), or any independent regulatory agency, but*
 18 *shall not include—*

19 **[(A) the General Accounting Office;**

20 **[(B) the Federal Election Commission;**

21 **[(C) the governments of the District of Co-**
 22 *lumbia and of the territories and possessions of*
 23 *the United States, and their various subdivi-*
 24 *sions; or*

1 **[(D)** *government-owned contractor-operated*
 2 *facilities, including laboratories engaged in na-*
 3 *tional defense research and production activities.*

4 **[(2)** *REGULATION.—The term “regulation”*
 5 *means an agency statement of general applicability*
 6 *and future effect designed to implement, interpret, or*
 7 *prescribe law or policy or describing the procedures or*
 8 *practice requirements of an agency. The term shall*
 9 *not include—*

10 **[(A)** *administrative actions governed by*
 11 *sections 556 and 557 of title 5, United States*
 12 *Code;*

13 **[(B)** *regulations issued with respect to a*
 14 *military or foreign affairs function of the United*
 15 *States; or*

16 **[(C)** *regulations related to agency organi-*
 17 *zation, management, or personnel.*

18 **[(b)** *ACCOUNTING STATEMENT.—*

19 **[(1)** *IN GENERAL.—(A) The President shall be*
 20 *responsible for implementing and administering the*
 21 *requirements of this section.*

22 **[(B)** *Every 2 years, no later than June of the*
 23 *second year, the President shall prepare and submit*
 24 *to Congress an accounting statement that estimates*
 25 *the annual costs of Federal regulatory programs and*

1 *corresponding benefits in accordance with this sub-*
2 *section.*

3 **[(2) YEARS COVERED BY ACCOUNTING STATE-**
4 *MENT.—Each accounting statement shall cover, at a*
5 *minimum, the 5 fiscal years beginning on October 1*
6 *of the year in which the report is submitted and may*
7 *cover any fiscal year preceding such fiscal years for*
8 *purpose of revising previous estimates.*

9 **[(3) TIMING AND PROCEDURES.—(A) The Presi-**
10 *dent shall provide notice and opportunity for com-*
11 *ment for each accounting statement. The President*
12 *may delegate to an agency the requirement to provide*
13 *notice and opportunity to comment for the portion of*
14 *the accounting statement relating to that agency.*

15 **[(B) The President shall propose the first ac-**
16 *counting statement under this subsection no later*
17 *than 2 years after the effective date of this Act and*
18 *shall issue the first accounting statement in final*
19 *form no later than 3 years after such effective date.*
20 *Such statement shall cover, at a minimum, each of*
21 *the fiscal years beginning after the effective date of*
22 *this Act.*

23 **[(4) CONTENT OF ACCOUNTING STATEMENT.—**
24 *(A) Each accounting statement shall contain esti-*
25 *mates of costs and benefits with respect to each fiscal*

1 *year covered by the statement in accordance with this*
 2 *paragraph. For each such fiscal year for which esti-*
 3 *mates were made in a previous accounting statement,*
 4 *the statement shall revise those estimates and state the*
 5 *reasons for the revisions.*

6 **[(B)(i)]** *An accounting statement shall estimate*
 7 *the costs of Federal regulatory programs by setting*
 8 *forth, for each year covered by the statement—*

9 **[(I)]** *the annual expenditure of national eco-*
 10 *nomical resources for each regulatory program;*
 11 *and*

12 **[(II)]** *such other quantitative and quali-*
 13 *tative measures of costs as the President consid-*
 14 *ers appropriate.*

15 **[(ii)]** *For purposes of the estimate of costs in the*
 16 *accounting statement, national economic resources*
 17 *shall include, and shall be listed under, at least the*
 18 *following categories:*

19 **[(I)]** *Private sector costs.*

20 **[(II)]** *Federal sector costs.*

21 **[(III)]** *State and local government costs.*

22 **[(C)]** *An accounting statement shall estimate the*
 23 *benefits of Federal regulatory programs by setting*
 24 *forth, for each year covered by the statement, such*
 25 *quantitative and qualitative measures of benefits as*

1 *the President considers appropriate. Any estimates of*
 2 *benefits concerning reduction in human health, safety,*
 3 *or environmental risks shall present the most plau-*
 4 *sible level of risk practical, along with a statement of*
 5 *the reasonable degree of scientific certainty.*

6 **[(c) ASSOCIATED REPORT TO CONGRESS.—**

7 **[(1) IN GENERAL.—***At the same time as the*
 8 *President submits an accounting statement under*
 9 *subsection (b), the President, acting through the Di-*
 10 *rector of the Office of Management and Budget, shall*
 11 *submit to Congress a report associated with the ac-*
 12 *counting statement (hereinafter referred to as an “as-*
 13 *sociated report”). The associated report shall contain,*
 14 *in accordance with this subsection—*

15 **[(A) analyses of impacts; and**

16 **[(B) recommendations for reform.**

17 **[(2) ANALYSES OF IMPACTS.—***The President*
 18 *shall include in the associated report the following:*

19 **[(A) The cumulative impact on the econ-**
 20 *omy of Federal regulatory programs covered in*
 21 *the accounting statement. Factors to be consid-*
 22 *ered in such report shall include impacts on the*
 23 *following:*

24 **[(i) The ability of State and local gov-**
 25 *ernments to provide essential services, in-*

cluding police, fire protection, and education.

【(ii) *Small business.*

【(iii) *Productivity.*

【(iv) *Wages.*

【(v) *Economic growth.*

【(vi) *Technological innovation.*

【(vii) *Consumer prices for goods and services.*

【(viii) *Such other factors considered appropriate by the President.*

【(B) *A summary of any independent analyses of impacts prepared by persons commenting during the comment period on the accounting statement.*

【(3) *RECOMMENDATIONS FOR REFORM.—The President shall include in the associated report the following:*

【(A) *A summary of recommendations of the President for reform or elimination of any Federal regulatory program or program element that does not represent sound use of national economic resources or otherwise is inefficient.*

【(B) *A summary of any recommendations for such reform or elimination of Federal regu-*

1 latory programs or program elements prepared
 2 by persons commenting during the comment pe-
 3 riod on the accounting statement.

4 **[(d) GUIDANCE FROM OFFICE OF MANAGEMENT AND**
 5 *BUDGET.*—The Director of the Office of Management and
 6 Budget shall, in consultation with the Council of Economic
 7 Advisers and the agencies, develop guidance for the agen-
 8 cies—

9 **[(1) to standardize measures of costs and bene-**
 10 *fits in accounting statements prepared pursuant to*
 11 *this section and section 3 of this Act, including—*

12 **[(A) detailed guidance on estimating the**
 13 *costs and benefits of major rules; and*

14 **[(B) general guidance on estimating the**
 15 *costs and benefits of all other rules that do not*
 16 *meet the thresholds for major rules; and*

17 **[(2) to standardize the format of the accounting**
 18 *statements.*

19 **[(e) RECOMMENDATIONS FROM CONGRESSIONAL**
 20 *BUDGET OFFICE.*—After each accounting statement and as-
 21 sociated report submitted to Congress, the Director of the
 22 Congressional Budget Office shall make recommendations
 23 to the President—

1 **[(1) for improving accounting statements pre-**
 2 *pared pursuant to this section, including rec-*
 3 *ommendations on level of detail and accuracy; and*

4 **[(2) for improving associated reports prepared**
 5 *pursuant to this section, including recommendations*
 6 *on the quality of analysis.*

7 **[(f) JUDICIAL REVIEW.—No requirements under this**
 8 *section shall be subject to judicial review in any manner.*

9 **[SEC. 8. EFFECTIVE DATE.**

10 **[Except as otherwise provided in this Act, this Act**
 11 *shall take effect 180 days after the date of the enactment*
 12 *of this Act.]*

13 **SECTION 1. SHORT TITLE.**

14 ***This Act may be cited as the “Comprehen-***
 15 ***sive Regulatory Reform Act of 1995”.***

16 **SEC. 2. DEFINITIONS.**

17 ***Section 551 of title 5, United States Code,***
 18 ***is amended—***

19 ***(1) in the matter preceding paragraph***
 20 ***(1), by striking “this subchapter” and in-***
 21 ***serting “this chapter and chapters 6, 7,***
 22 ***and 8”;***

23 ***(2) in paragraph (13), by striking***
 24 ***“and”;***

1 ***(3) in paragraph (14), by striking the***
2 ***period at the end and inserting “; and”;***
3 ***and***

4 ***(4) by adding at the end the following***
5 ***new paragraph:***

6 ***“(15) ‘Director’ means the Director of***
7 ***the Office of Management and Budget.”.***

8 ***SEC. 3. RULEMAKING.***

9 ***Section 553 of title 5, United States Code,***
10 ***is amended to read as follows:***

11 ***“§ 553. Rulemaking***

12 ***“(a) This section applies to every rule-***
13 ***making, according to the provisions thereof,***
14 ***except to the extent that there is involved—***

15 ***“(1) a matter pertaining to a military***
16 ***or foreign affairs function of the United***
17 ***States;***

18 ***“(2) a matter relating to the manage-***
19 ***ment and personnel practices of an agen-***
20 ***cy;***

21 ***“(3) an interpretive rule, general***
22 ***statement of policy, guidance, or rule of***
23 ***agency organization, procedure, or prac-***
24 ***tice that is not generally applicable and***

1 *does not alter or create rights or obliga-*
2 *tions of persons outside the agency; or*

3 *“(4) a rule relating to the acquisition,*
4 *management, or disposal by an agency of*
5 *real or personal property, or of services,*
6 *that is promulgated in compliance with*
7 *criteria and procedures established by the*
8 *Administrator of General Services.*

9 *“(b)(1) General notice of proposed rule-*
10 *making shall be published in the Federal Reg-*
11 *ister, unless all persons subject thereto are*
12 *named and either personally served or other-*
13 *wise have actual notice of the proposed rule-*
14 *making in accordance with law. Each notice*
15 *of proposed rulemaking shall include—*

16 *“(A) a statement of the time, place,*
17 *and nature of public rulemaking proceed-*
18 *ings;*

19 *“(B) a succinct explanation of the*
20 *need for and specific objectives of the pro-*
21 *posed rule, including an explanation of*
22 *the agency’s determination of whether or*
23 *not the rule is a major rule within the*
24 *meaning of section 621(4);*

1 ***“(C) an explanation of the specific***
2 ***statutory interpretation under which a***
3 ***rule is proposed, including an expla-***
4 ***nation of—***

5 ***“(i) whether the interpretation is***
6 ***expressly required by the text of the***
7 ***statute; or***

8 ***“(ii) if the interpretation is not ex-***
9 ***pressly required by the text of the stat-***
10 ***ute, an explanation that the interpre-***
11 ***tation is within the range of permis-***
12 ***sible interpretations of the statute as***
13 ***identified by the agency, and an ex-***
14 ***planation why the interpretation se-***
15 ***lected by the agency is the agency’s***
16 ***preferred interpretation;***

17 ***“(D) the proposed provisions of the***
18 ***rule;***

19 ***“(E) a summary of any initial analysis***
20 ***of the proposed rule required to be pre-***
21 ***pared or issued pursuant to chapter 6;***

22 ***“(F) a statement that the agency seeks***
23 ***proposals from the public and from State***
24 ***and local governments for alternative***
25 ***methods to accomplish the objectives of***

1 *the rulemaking that are more effective or*
2 *less burdensome than the approach used*
3 *in the proposed rule;*

4 *“(G) a description of any data, meth-*
5 *odologies, reports, studies, scientific eval-*
6 *uations, or other similar information*
7 *available to the agency for the rule-*
8 *making, including an identification of*
9 *each author or source of such information*
10 *and the purposes for which the agency*
11 *plans to rely on such information; and*

12 *“(H) a statement specifying where the*
13 *file of the rulemaking proceeding main-*
14 *tained pursuant to subsection (f) may be*
15 *inspected and how copies of the items in*
16 *the file may be obtained.*

17 *“(2) Except when notice or hearing is re-*
18 *quired by statute, a final rule may be adopted*
19 *and may become effective without prior com-*
20 *pliance with this subsection and subsections*
21 *(c) and (f) if—*

22 *“(A) the agency for good cause finds*
23 *that providing notice and public proce-*
24 *dure thereon before the rule becomes effec-*
25 *tive is contrary to an important public in-*

1 *terest or is unnecessary due to the insig-*
2 *nificant impact of the rule;*

3 *“(B) the agency publishes the rule in*
4 *the Federal Register with such finding*
5 *and a succinct explanation of the reasons*
6 *therefor; and*

7 *“(C) the agency complies with this*
8 *subsection and subsections (c) and (f) to*
9 *the maximum extent feasible prior to the*
10 *promulgation of the final rule, and fully*
11 *complies with such provisions as soon as*
12 *reasonably practicable after the promul-*
13 *gation of the rule.*

14 *“(3) Whenever the provisions of a final rule*
15 *that an agency plans to adopt are so different*
16 *from the provisions of the proposed rule that*
17 *the original notice of proposed rulemaking did*
18 *not fairly apprise the public of the issues ulti-*
19 *mately to be resolved in the rulemaking or of*
20 *the substance of the rule, the agency shall pub-*
21 *lish in the Federal Register a notice of the*
22 *final rule the agency plans to adopt, together*
23 *with the information relevant to such rule that*
24 *is required by the applicable provisions of this*
25 *section and that has not previously been pub-*

1 *lished in the Federal Register. The agency*
2 *shall allow a reasonable period for comment*
3 *on such final rule.*

4 *“(c)(1) After providing the notice required*
5 *by this section, the agency shall give interested*
6 *persons not less than 60 days to participate in*
7 *the rulemaking through the submission of*
8 *written data, views, or arguments.*

9 *“(2)(A) To collect relevant information,*
10 *and to identify and elicit full and representa-*
11 *tive public comment on the significant issues*
12 *of a particular rulemaking, the agency may*
13 *use such other procedures as the agency deter-*
14 *mines are appropriate, including—*

15 *“(i) the publication of an advance no-*
16 *tice of proposed rulemaking;*

17 *“(ii) the provision of notice, in forms*
18 *which are more direct than notice pub-*
19 *lished in the Federal Register, to persons*
20 *who would be substantially affected by the*
21 *proposed rule, but who are unlikely to re-*
22 *ceive notice of the proposed rulemaking*
23 *through the Federal Register;*

24 *“(iii) the provision of opportunities for*
25 *oral presentation of data, views, informa-*

1 *tion, or rebuttal arguments at informal*
2 *public hearings, which may be held in the*
3 *District of Columbia and other locations;*

4 *“(iv) the provision of summaries, ex-*
5 *planatory materials, or other technical*
6 *information in response to public inquir-*
7 *ies concerning the issues involved in the*
8 *rulemaking; and*

9 *“(v) the adoption or modification of*
10 *agency procedural rules to reduce the cost*
11 *or complexity of participation in a rule-*
12 *making.*

13 *“(B) The decision of an agency to use or not*
14 *to use such other procedures in a rulemaking*
15 *pursuant to this paragraph shall not be sub-*
16 *ject to judicial review.*

17 *“(3) To ensure an orderly and expeditious*
18 *proceeding, an agency may establish reason-*
19 *able procedures to regulate the course of infor-*
20 *mal public hearings under paragraphs (1)*
21 *and (2), including the designation of rep-*
22 *resentatives to make oral presentations or en-*
23 *gage in direct or cross-examination on behalf*
24 *of several parties with a common interest in a*

1 *rulemaking. Transcripts shall be made of all*
2 *such public hearings.*

3 *“(4) An agency shall publish any final rule*
4 *it adopts in the Federal Register, together with*
5 *a concise statement of the basis and purpose*
6 *of the rule and a statement of when the rule*
7 *may become effective. The statement of basis*
8 *and purpose shall include—*

9 *“(A) an explanation of the need for,*
10 *objectives of, and specific statutory au-*
11 *thority for, the rule;*

12 *“(B) a discussion of, and response to,*
13 *any significant factual or legal issues*
14 *raised by the comments on the proposed*
15 *rule prior to its promulgation, including*
16 *a description of the reasonable alter-*
17 *natives to the rule proposed by the agency*
18 *and by interested persons, and the reasons*
19 *why each such alternative was rejected;*

20 *“(C)(i) an explanation of whether the*
21 *specific statutory interpretation upon*
22 *which the rule is based is expressly re-*
23 *quired by the text of the statute; or*

24 *“(ii) if the specific statutory interpre-*
25 *tation upon which the rule is based is not*

1 *expressly required by the text of the statute,*
2 *an explanation that the interpretation*
3 *is within the range of permissible interpretations*
4 *of the statute as identified by the agency,*
5 *and why the agency has rejected other*
6 *interpretations proposed in comments to the agency;*

8 *“(D) an explanation of how the factual*
9 *conclusions upon which the rule is based*
10 *are substantially supported in the rulemaking*
11 *file maintained pursuant to subsection (f); and*

13 *“(E) a summary of any final analysis*
14 *of the rule required to be prepared or issued*
15 *pursuant to chapter 6.*

16 *“(5) The provisions of sections 556 and 557*
17 *shall apply in lieu of this subsection in the*
18 *case of rules that are required by statute to be*
19 *made on the record after opportunity for an*
20 *agency hearing.*

21 *“(d) An agency shall publish the final rule*
22 *in the Federal Register not less than 60 days*
23 *before the effective date of such rule. An agency*
24 *may make a rule effective in less than 60*
25 *days after publication in the Federal Register*

1 *if the rule grants or recognizes an exemption,*
 2 *relieves a restriction, or if the agency for good*
 3 *cause finds that such a delay in the effective*
 4 *date would be contrary to an important public*
 5 *interest and publishes such finding and an ex-*
 6 *planation of the reasons therefor, with the*
 7 *final rule.*

8 “(e)(1) *Each agency shall give an inter-*
 9 *ested person the right to petition for the issu-*
 10 *ance, amendment, or repeal of a rule.*

11 “(2) *Each person subject to a major rule*
 12 *may petition—*

13 “(A) *for the issuance, amendment, or*
 14 *repeal of such rule;*

15 “(B) *for the amendment or repeal of*
 16 *an interpretive rule or general statement*
 17 *of policy or guidance;*

18 “(C) *for an interpretation regarding*
 19 *the meaning of the rule, interpretive rule,*
 20 *general statement of policy, or guidance;*
 21 *and*

22 “(D) *for a variance or exemption from*
 23 *the terms of the rule.*

24 “(3)(A) *Any person subject to a rule, inter-*
 25 *pretive rule, general statement of policy, or*

1 *guidance may petition an agency for the*
2 *amendment or repeal of any rule, interpretive*
3 *rule, general statement of policy, or guidance.*

4 “(B) *If such petition presents a reasonable*
5 *likelihood that, considering its future impact,*
6 *the rule, interpretive rule, general statement*
7 *of policy, or guidance is, or has the effect of,*
8 *a major rule within the meaning of section*
9 *621(4), and its amendment or repeal is re-*
10 *quired to satisfy the decisional criteria of sec-*
11 *tion 624, the agency shall grant the petition*
12 *and shall, within one year, conduct a cost-ben-*
13 *efit analysis under chapter 6.*

14 “(C) *If, considering its future impact, the*
15 *rule, interpretive rule, general statement of*
16 *policy, or guidance does not satisfy the re-*
17 *quirements of chapter 6, including the*
18 *decisional criteria set forth in section 624, the*
19 *agency shall take immediate action either to*
20 *revoke or to amend the rule, interpretive rule,*
21 *general statement of policy, or guidance to*
22 *conform it to the requirements of chapter 6, in-*
23 *cluding the decisional criteria in section 624.*

24 “(4) *The agency shall grant or deny a peti-*
25 *tion made pursuant to this subsection, and*

1 *give written notice of its determination to the*
2 *petitioner, with reasonable promptness, but in*
3 *no event later than 180 days after the petition*
4 *was received by the agency. The written notice*
5 *of the agency's determination shall include an*
6 *explanation of the determination and a re-*
7 *sponse to each factual and legal claim that*
8 *forms the basis of the petition. A decision to*
9 *deny a petition shall be subject to judicial re-*
10 *view immediately upon denial, as final agency*
11 *action under the statute granting the agency*
12 *authority to carry out its action.*

13 *“(5) Following a decision to grant or deny*
14 *a petition to conduct a cost-benefit analysis for*
15 *a rule, interpretive rule, general statement of*
16 *policy, or guidance under this subsection, no*
17 *further petition for such rule, interpretive*
18 *rule, general statement of policy, or guidance,*
19 *submitted by the same person, shall be consid-*
20 *ered by any agency unless such petition is*
21 *based on a change in a fact, circumstance, or*
22 *provision of law underlying or otherwise relat-*
23 *ed to the rule, interpretive rule, general state-*
24 *ment of policy, or guidance occurring since the*
25 *initial petition was granted or denied, that*

1 *warrants the amendment or repeal of the rule,*
2 *interpretive rule, general statement of policy,*
3 *or guidance.*

4 “(f)(1) *The agency shall maintain a file for*
5 *each rulemaking proceeding conducted pursu-*
6 *ant to this section and shall maintain a cur-*
7 *rent index to such file. The file and the mate-*
8 *rial excluded from the file pursuant to para-*
9 *graph (4) shall constitute the rulemaking*
10 *record for purposes of judicial review. Except*
11 *as provided in paragraph (4), the file shall be*
12 *made available to the public beginning on the*
13 *date on which the agency makes an initial*
14 *publication concerning the rule.*

15 “(2) *The rulemaking file shall include—*

16 “(A) *the notice of proposed rule-*
17 *making, any supplement to, or modifica-*
18 *tion or revision of, such notice, and any*
19 *advance notice of proposed rulemaking;*

20 “(B) *copies of all written comments re-*
21 *ceived on the proposed rule;*

22 “(C) *a transcript of any public hear-*
23 *ing conducted on the rulemaking;*

24 “(D) *copies, or an identification of the*
25 *place at which copies may be obtained, of*

1 *all material described by the agency pur-*
2 *suant to subsection (b)(1)(G) and of other*
3 *factual and methodological material not*
4 *described by the agency pursuant to such*
5 *subsection that pertains directly to the*
6 *rulemaking and that was available to the*
7 *agency in connection with the rule-*
8 *making, or that was submitted to or pre-*
9 *pared by or for the agency in connection*
10 *with the rulemaking; and*

11 *“(E) any statement, description, analy-*
12 *sis, or any other material that the agency*
13 *is required to prepare or issue in connec-*
14 *tion with the rulemaking, including any*
15 *analysis prepared or issued pursuant to*
16 *chapter 6.*

17 *“(3) The agency shall place the materials*
18 *described in paragraph (2) in the file as soon*
19 *as practicable after such materials become*
20 *available to the agency.*

21 *“(4) The file required by paragraph (1)*
22 *need not include any material that need not be*
23 *made available to the public under section*
24 *552(b)(4) if the agency includes in such file a*
25 *statement that notes the existence of such ma-*

1 *terial and the basis upon which the material*
2 *is exempt from public disclosure under such*
3 *section. The agency may not substantially rely*
4 *on any such material in formulating a rule*
5 *unless it makes the substance of such material*
6 *available for adequate comment by interested*
7 *persons. The agency may use summaries, ag-*
8 *gregations of data, or other appropriate mech-*
9 *anisms to protect the confidentiality of such*
10 *material to the maximum extent possible.*

11 *“(5) No court shall hold unlawful or set*
12 *aside an agency rule because of a violation of*
13 *this subsection unless the court finds that such*
14 *violation has precluded fair public consider-*
15 *ation of a material issue of the rulemaking*
16 *taken as a whole. Judicial review of compli-*
17 *ance or noncompliance with this subsection*
18 *shall be limited to review of action or inaction*
19 *on the part of an agency.*

20 *“(g) Notwithstanding any other provision*
21 *of law, this section shall apply to and supple-*
22 *ment the procedures governing rulemaking*
23 *under statutes that are not generally subject*
24 *to this section.*

1 ***“(h) Nothing in this section authorizes the***
 2 ***use of appropriated funds available to any***
 3 ***agency to pay the attorney’s fees or other ex-***
 4 ***penses of persons participating or intervening***
 5 ***in agency proceedings.”.***

6 ***SEC. 4. ANALYSIS OF AGENCY RULES.***

7 ***(a) IN GENERAL.—Chapter 6 of title 5, Unit-***
 8 ***ed States Code, is amended by adding at the***
 9 ***end the following:***

10 ***“SUBCHAPTER II—ANALYSIS OF AGENCY***
 11 ***RULES***

12 ***“§621. Definitions***

13 ***“For purposes of this subchapter—***

14 ***“(1) the term ‘benefit’ means the rea-***
 15 ***sonably identifiable significant incremen-***
 16 ***tal benefits, including social and eco-***
 17 ***nomie benefits, that are expected to result***
 18 ***directly or indirectly from implementation***
 19 ***of a rule or an alternative to a rule;***

20 ***“(2) the term ‘cost’ means the reason-***
 21 ***ably identifiable significant incremental***
 22 ***costs and adverse effects, including social***
 23 ***and economic costs, reduced consumer***
 24 ***choice, substitution effects, and impeded***
 25 ***technological advancement, that are ex-***

1 *pected to result directly or indirectly from*
2 *implementation of, or compliance with, a*
3 *rule or an alternative to a rule;*

4 *“(3) the term ‘cost-benefit analysis’*
5 *means an evaluation of the costs and ben-*
6 *efits of a rule, quantified to the extent fea-*
7 *sible and appropriate and otherwise*
8 *qualitatively described, that is prepared*
9 *in accordance with the requirements of*
10 *this subchapter at the level of detail ap-*
11 *propriate and practicable for reasoned*
12 *decisionmaking on the matter involved,*
13 *taking into consideration the significance*
14 *and complexity of the decision and any*
15 *need for expedition;*

16 *“(4)(A) the term ‘major rule’ means—*

17 *“(i) a rule or a group of closely re-*
18 *lated rules that the agency proposing*
19 *the rule, the Director, or a designee of*
20 *the President reasonably determines*
21 *is likely to have a gross annual effect*
22 *on the economy of \$50,000,000 or more*
23 *in reasonably quantifiable increased*
24 *direct and indirect costs, or has a sig-*

1 *nificant impact on a sector of the*
2 *economy; or*

3 *“(ii) a rule or a group of closely*
4 *related rules that is otherwise des-*
5 *ignated a major rule by the agency*
6 *proposing the rule, the Director, or a*
7 *designee of the President on the*
8 *ground that the rule is likely to result*
9 *in—*

10 *“(I) a substantial increase in*
11 *costs or prices for wage earners,*
12 *consumers, individual industries,*
13 *nonprofit organizations, Federal,*
14 *State, or local government agen-*
15 *cies, or geographic regions;*

16 *“(II) significant adverse ef-*
17 *fects on competition, employment,*
18 *investment, productivity, innova-*
19 *tion, health, safety, or the environ-*
20 *ment, or the ability of enterprises*
21 *whose principal places of business*
22 *are in the United States to com-*
23 *pete in domestic or export mar-*
24 *kets;*

1 ***“(III) a serious inconsistency***
2 ***or interference with an action***
3 ***taken or planned by another agen-***
4 ***cy;***

5 ***“(IV) the material alteration***
6 ***of the budgetary impact of entitle-***
7 ***ments, grants, user fees, or loan***
8 ***programs, or the rights and obli-***
9 ***gations of recipients thereof; or***

10 ***“(V) disproportionate costs to***
11 ***a class of persons within the regu-***
12 ***lated sector, and relatively severe***
13 ***economic consequences for the***
14 ***class;***

15 ***“(B) the term ‘major rule’ does not in-***
16 ***clude—***

17 ***“(i) a rule that involves the inter-***
18 ***nal revenue laws of the United States;***
19 ***or***

20 ***“(ii) a rule or agency action that***
21 ***authorizes the introduction into, or***
22 ***removal from, commerce, or recog-***
23 ***nizes the marketable status, of a prod-***
24 ***uct;***

1 ***“(5) the term ‘market-based mecha-***
2 ***nism’ means a regulatory program that—***

3 ***“(A) imposes legal accountability***
4 ***for the achievement of an explicit reg-***
5 ***ulatory objective on each regulated***
6 ***person;***

7 ***“(B) affords maximum flexibility***
8 ***to each regulated person in complying***
9 ***with mandatory regulatory objectives,***
10 ***which flexibility shall, where feasible***
11 ***and appropriate, include, but not be***
12 ***limited to, the opportunity to transfer***
13 ***to, or receive from, other persons, in-***
14 ***cluding for cash or other legal consid-***
15 ***eration, increments of compliance re-***
16 ***sponsibility established by the pro-***
17 ***gram; and***

18 ***“(C) permits regulated persons to***
19 ***respond freely to changes in general***
20 ***economic conditions and in economic***
21 ***circumstances directly pertinent to***
22 ***the regulatory program without af-***
23 ***fecting the achievement of the pro-***
24 ***gram’s explicit regulatory mandates;***

1 ***“(6) the term ‘performance-based***
2 ***standards’ means requirements, expressed***
3 ***in terms of outcomes or goals rather than***
4 ***mandatory means of achieving outcomes***
5 ***or goals, that permit the regulated entity***
6 ***discretion to determine how best to meet***
7 ***specific requirements in particular cir-***
8 ***cumstances;***

9 ***“(7) the term ‘reasonable alternatives’***
10 ***means the range of regulatory options***
11 ***that the agency has discretion to consider***
12 ***under the text of the statute granting***
13 ***rulemaking authority, interpreted, to the***
14 ***maximum extent possible, to embrace the***
15 ***broadest range of options that satisfy the***
16 ***decisional criteria of section 624(b); and***

17 ***“(8) the term ‘rule’ has the same***
18 ***meaning as in section 551(4), and—***

19 ***“(A) includes any statement of***
20 ***general applicability that alters or***
21 ***creates rights or obligations of per-***
22 ***sons outside the agency; and***

23 ***“(B) does not include—***

24 ***“(i) a rule of particular appli-***
25 ***cability that approves or pre-***

1 *scribes the future rates, wages,*
2 *prices, services, corporate or fi-*
3 *nancial structures, reorganiza-*
4 *tions, mergers, acquisitions, ac-*
5 *counting practices, or disclosures*
6 *bearing on any of the foregoing;*

7 *“(ii) a rule relating to mone-*
8 *tary policy or to the safety or*
9 *soundness of Federally insured de-*
10 *pository institutions or any affili-*
11 *ate of such an institution (as de-*
12 *fin ed in section 2(k) of the Bank*
13 *Holding Company Act of 1956),*
14 *credit unions, Federal Home Loan*
15 *Banks, government sponsored*
16 *housing enterprises, farm credit*
17 *institutions, foreign banks that*
18 *operate in the United States and*
19 *their affiliates, branches, agen-*
20 *cies, commercial lending compa-*
21 *nies, or representative offices, (as*
22 *those terms are defined in section*
23 *1 of the International Banking Act*
24 *of 1978); or*

1 ***“(iii) a rule relating to the***
2 ***payment system or the protection***
3 ***of deposit insurance funds or the***
4 ***farm credit insurance fund.***

5 ***“§ 622. Rulemaking cost-benefit analysis***

6 ***“(a) Prior to publishing notice of a pro-***
7 ***posed rulemaking for any rule (or, in the case***
8 ***of a notice of a proposed rulemaking that has***
9 ***been published on or before the date of enact-***
10 ***ment of this subchapter, not later than 30 days***
11 ***after such date of enactment), each agency***
12 ***shall determine whether the rule is or is not***
13 ***a major rule within the meaning of section***
14 ***621(4)(A)(i) and, if it is not, whether it should***
15 ***be designated a major rule under section***
16 ***621(4)(A)(ii). For the purpose of any such de-***
17 ***termination or designation, a group of closely***
18 ***related rules shall be considered as one rule.***

19 ***“(b)(1) If an agency has determined that a***
20 ***rule is not a major rule within the meaning of***
21 ***section 621(4)(A)(i) and has not designated the***
22 ***rule a major rule within the meaning of sec-***
23 ***tion 621(4)(A)(ii), the Director or a designee of***
24 ***the President may, as appropriate, determine***
25 ***that the rule is a major rule or designate the***

1 *rule a major rule not later than 30 days after*
2 *the publication of the notice of proposed rule-*
3 *making for the rule (or, in the case of a notice*
4 *of proposed rulemaking that has been pub-*
5 *lished on or before the date of enactment of*
6 *this subchapter, not later than 60 days after*
7 *such date of enactment).*

8 “(2) *Such determination or designation*
9 *shall be published in the Federal Register, to-*
10 *gether with a succinct statement of the basis*
11 *for the determination or designation.*

12 “(c)(1)(A) *When the agency publishes a no-*
13 *tice of proposed rulemaking for a major rule,*
14 *the agency shall issue and place in the rule-*
15 *making file an initial cost-benefit analysis,*
16 *and shall include a summary of such analysis*
17 *in the notice of proposed rulemaking.*

18 “(B)(i) *When the Director or a designee of*
19 *the President has published a determination*
20 *or designation that a rule is a major rule after*
21 *the publication of the notice of proposed rule-*
22 *making for the rule, the agency shall promptly*
23 *issue and place in the rulemaking file an ini-*
24 *tial cost-benefit analysis for the rule and shall*

1 *publish in the Federal Register a summary of*
2 *such analysis.*

3 *“(ii) Following the issuance of an initial*
4 *cost-benefit analysis under clause (i), the*
5 *agency shall give interested persons an oppor-*
6 *tunity to comment in the same manner as if the*
7 *initial cost-benefit analysis had been issued*
8 *with the notice of proposed rulemaking.*

9 *“(2) Each initial cost-benefit analysis shall*
10 *contain—*

11 *“(A) an analysis of the benefits of the*
12 *proposed rule, and an explanation of how*
13 *the agency anticipates each benefit will be*
14 *achieved by the proposed rule, including a*
15 *description of the persons or classes of*
16 *persons likely to receive such benefits;*

17 *“(B) an analysis of the costs of the*
18 *proposed rule, and an explanation of how*
19 *the agency anticipates each such cost will*
20 *result from the proposed rule, including a*
21 *description of the persons or groups of*
22 *persons likely to bear such costs;*

23 *“(C) an identification (including an*
24 *analysis of the costs and benefits) of rea-*
25 *sonable alternatives that the agency has*

1 *discretion to adopt under the decisional*
2 *criteria of the statute granting the rule-*
3 *making authority, as supplemented by the*
4 *decisional criteria in section 624, for*
5 *achieving identified benefits, including,*
6 *where appropriate, alternatives that—*

7 *“(i) require no government action;*

8 *“(ii) will accommodate differences*
9 *among geographic regions and among*
10 *persons with differing levels of re-*
11 *sources with which to comply; and*

12 *“(iii) employ voluntary or perform-*
13 *ance-based standards, market-based*
14 *mechanisms, or other flexible regu-*
15 *latory alternatives that permit the*
16 *greatest flexibility in achieving the*
17 *identified benefits of the proposed*
18 *rule;*

19 *“(D) an assessment of the feasibility of*
20 *establishing a regulatory program that*
21 *operates through the application of vol-*
22 *untary programs, voluntary consensus*
23 *standards, performance-based standards,*
24 *market-based mechanisms, or other flexi-*
25 *ble regulatory alternatives;*

1 ***“(E) in any case in which the proposed***
2 ***rule is based on one or more scientific***
3 ***evaluations, scientific information, or a***
4 ***risk assessment, or is subject to the risk***
5 ***assessment requirements of subchapter***
6 ***III, a description of the actions under-***
7 ***taken by the agency to verify the quality,***
8 ***reliability, and relevance of such sci-***
9 ***entific evaluations or scientific informa-***
10 ***tion in accordance with the requirements***
11 ***of subchapter III;***

12 ***“(F) an analysis, to the extent prac-***
13 ***ticable, of the effect of the rule on—***

14 ***“(i) the cumulative burden of com-***
15 ***pliance with the rule and other exist-***
16 ***ing regulations on persons complying***
17 ***with it; and***

18 ***“(ii) the net effect on small busi-***
19 ***nesses with fewer than 100 employees,***
20 ***including employment in such busi-***
21 ***nesses;***

22 ***“(G) an analysis of whether the identi-***
23 ***fied benefits of the proposed rule justify***
24 ***the identified costs of the proposed rule,***
25 ***and an analysis of whether the proposed***

1 *rule will achieve greater net benefits or,*
2 *where applicable, lower net costs, than*
3 *any of the alternatives to the proposed*
4 *rule, including alternatives identified in*
5 *accordance with subparagraphs (C) and*
6 *(D).*

7 *“(d)(1) When the agency publishes a final*
8 *major rule, the agency shall also issue and*
9 *place in the rulemaking file a final cost-bene-*
10 *fit analysis, and shall include a summary of*
11 *the analysis in the statement of basis and pur-*
12 *pose.*

13 *“(2) Each final cost-benefit analysis shall*
14 *contain—*

15 *“(A) a description and comparison of*
16 *the benefits and costs of the rule and of*
17 *the reasonable alternatives to the rule de-*
18 *scribed in the rulemaking, including the*
19 *flexible regulatory alternatives identified*
20 *pursuant to subsection (c)(2) (C) and (D);*
21 *and*

22 *“(B) an analysis, based upon the rule-*
23 *making record considered as a whole, of—*

24 *“(i) whether the benefits of the*
25 *rule justify the costs of the rule; and*

1 ***“(ii) whether the rule will achieve***
2 ***greater net benefits or, where section***
3 ***624(c) applies, lower net costs, than***
4 ***any of the reasonable alternatives***
5 ***that the agency has discretion to***
6 ***adopt under the decisional criteria of***
7 ***the statute granting the rulemaking***
8 ***authority, as supplemented by the***
9 ***decisional criteria in section 624, for***
10 ***achieving identified benefits, includ-***
11 ***ing, where appropriate, alternatives***
12 ***referred to in subsection (c)(2) (C) and***
13 ***(D).***

14 ***“(e)(1)(A) The analysis of the benefits and***
15 ***costs of a proposed and a final rule required***
16 ***under this section shall include, to the extent***
17 ***feasible, a quantification or numerical esti-***
18 ***mate of the quantifiable benefits and costs.***
19 ***Such quantification or numerical estimate***
20 ***shall be made in the most appropriate unit of***
21 ***measurement, using comparable assumptions,***
22 ***including time periods, shall specify the***
23 ***ranges of predictions, and shall explain the***
24 ***margins of error involved in the quantifica-***
25 ***tion methods and in the estimates used. An***

1 *agency shall describe the nature and extent of*
2 *the nonquantifiable benefits and costs of a*
3 *final rule pursuant to this section in as precise*
4 *and succinct a manner as possible. An agency*
5 *shall not be required to make such evaluation*
6 *primarily on a mathematical or numerical*
7 *basis.*

8 *“(B) Where practicable and appropriate,*
9 *the description of the benefits and costs of a*
10 *proposed and final rule required under this*
11 *section shall describe such benefits and costs*
12 *on an industry by industry basis.*

13 *“(2)(A) In evaluating and comparing costs*
14 *and benefits and in evaluating the risk assess-*
15 *ment information developed pursuant to sub-*
16 *chapter III, the agency shall not rely on cost,*
17 *benefit, or risk assessment information that is*
18 *not accompanied by relevant information that*
19 *would enable the agency and other persons in-*
20 *terested in the rulemaking to assess the accu-*
21 *racy, reliability, and uncertainty factors ap-*
22 *plicable to such information.*

23 *“(B) The agency evaluations of the rela-*
24 *tionships of the benefits of a proposed and*

1 *final rule to its costs shall be clearly articu-*
2 *lated in accordance with this section.*

3 “(f) *The preparation of the initial or final*
4 *cost-benefit analysis required by this section*
5 *shall only be performed by an officer or em-*
6 *ployee of the agency. The preceding sentence*
7 *shall not preclude a person outside the agency*
8 *from gathering data or information to be used*
9 *by the agency in preparing any such cost-bene-*
10 *fit analysis or from providing an explanation*
11 *sufficient to permit the agency to analyze such*
12 *data or information. If any such data or infor-*
13 *mation is gathered or explained by a person*
14 *outside the agency, the agency shall specifi-*
15 *cally identify in the initial or final cost-benefit*
16 *analysis the data or information gathered or*
17 *explained and the person who gathered or ex-*
18 *plained it, and shall describe the arrangement*
19 *by which the information was procured by the*
20 *agency, including the total amount of funds*
21 *expended for such procurement.*

22 *“§623. Petition for cost-benefit analysis*

23 “(a)(1) *Any person subject to a major rule*
24 *may petition the relevant agency, the Director,*
25 *or a designee of the President to perform a*

1 *cost-benefit analysis under this subchapter for*
2 *the major rule, including a major rule in effect*
3 *on the date of enactment of this subchapter for*
4 *which a cost-benefit analysis pursuant to such*
5 *subchapter has not been performed, regardless*
6 *of whether a cost-benefit analysis was pre-*
7 *viously performed to meet requirements im-*
8 *posed before the date of enactment of this sub-*
9 *chapter.*

10 “(2) *The petition shall identify with rea-*
11 *sonable specificity the major rule to be re-*
12 *viewed and the amendment or repeal re-*
13 *quested.*

14 “(3) *The agency, the Director, or a designee*
15 *of the President shall grant the petition if the*
16 *petition shows that there is a reasonable like-*
17 *lihood that, considering the future impact of*
18 *the rule—*

19 “(A) *the rule is a major rule; and*

20 “(B) *the proposed amendment or re-*
21 *peal of the rule is required to satisfy the*
22 *decisional criteria of section 624.*

23 “(4) *A decision to grant, or final agency ac-*
24 *tion to deny, a petition under this subsection*

1 *shall be made not later than 180 days after*
2 *submittal.*

3 *“(5) Following a decision to grant or deny*
4 *a petition to conduct a cost-benefit analysis for*
5 *a rule under this subsection, no further peti-*
6 *tion for such rule, submitted by the same per-*
7 *son, shall be considered by any agency, the Di-*
8 *rector, or a designee of the President, unless*
9 *such petition is based on a change in a fact,*
10 *circumstance, or provision of law underlying*
11 *or otherwise related to the rule occurring since*
12 *the initial petition was granted or denied, that*
13 *warrants the amendment or repeal of the rule.*

14 *“(b) Not later than 1 year after the date on*
15 *which a petition has been granted for a major*
16 *rule under subsection (a), the agency shall*
17 *conduct a cost-benefit analysis in accordance*
18 *with this subchapter, and shall propose*
19 *amendments to, or repeal of, the rule if re-*
20 *quired by the decisional criteria set forth in*
21 *section 624.*

22 *“(c) For purposes of this section, the term*
23 *‘major rule’ means any major rule or portion*
24 *thereof.*

1 ***“(d)(1) Any person may petition the rel-***
2 ***evant agency to withdraw, as contrary to this***
3 ***subchapter, any agency interpretive rule, guid-***
4 ***ance, or general statement of policy that would***
5 ***have the effect of a major rule if the interpre-***
6 ***tive rule, guidance, or general statement of***
7 ***policy had been adopted as a rule.***

8 ***“(2) The petition shall identify with rea-***
9 ***sonable specificity why the interpretive rule,***
10 ***guidance, or general statement of policy would***
11 ***have the effect of a major rule if adopted as***
12 ***a rule.***

13 ***“(3) The agency shall grant the petition if***
14 ***the petition shows that there is a reasonable***
15 ***likelihood that the guidance or general state-***
16 ***ment of policy would have the effect of a major***
17 ***rule if adopted as a rule.***

18 ***“(4) A decision to grant, or final agency ac-***
19 ***tion to deny, a petition under this subsection***
20 ***shall be made not later than 180 days after the***
21 ***petition is submitted.***

22 ***“(e) For each interpretative rule, guid-***
23 ***ance, or general statement of policy for which***
24 ***a petition has been granted under subsection***
25 ***(d), the agency shall—***

1 ***“(1) immediately withdraw the inter-***
2 ***pretive rule, guidance, or general state-***
3 ***ment of policy; or***

4 ***“(2) within one year, propose a rule in***
5 ***compliance with this subchapter incor-***
6 ***porating, with such modifications as the***
7 ***agency considers appropriate, the regu-***
8 ***latory standards or criteria contained in***
9 ***such interpretive rule, general statement***
10 ***of policy, or guidance.***

11 ***“(f) Upon withdrawing an interpretive***
12 ***rule, guidance, or general statement of policy,***
13 ***or where such interpretive rule, guidance, or***
14 ***general statement of policy is not withdrawn***
15 ***and a final rule is not promulgated within 2***
16 ***years of granting a petition under subsection***
17 ***(d), the agency shall be prohibited from enforc-***
18 ***ing against any person the regulatory stand-***
19 ***ards or criteria contained in such interpretive***
20 ***rule, guidance, or general statement of policy,***
21 ***unless and until they are included in a rule***
22 ***promulgated in accordance with this sub-***
23 ***chapter.***

24 ***“(g)(1) Any person subject to a major rule***
25 ***may petition the relevant agency to modify or***

1 *waive the specific requirements of the major*
2 *rule and to authorize such person to dem-*
3 *onstrate compliance through alternative*
4 *means not otherwise permitted by the major*
5 *rule. The petition shall identify with reason-*
6 *able specificity the requirements for which the*
7 *waiver is sought and the alternative means of*
8 *compliance being proposed.*

9 “(2) *The agency shall grant the petition if*
10 *the petition shows that there is a reasonable*
11 *likelihood that the proposed alternative*
12 *means of compliance would achieve the spe-*
13 *cific benefits of the major rule with an equiva-*
14 *lent or greater level of protection of health,*
15 *safety, and the environment than would be*
16 *provided by the major rule, and would not im-*
17 *pose an undue burden on the agency that*
18 *would be responsible for enforcing such alter-*
19 *native means of compliance.*

20 “(3) *Following a decision to grant or deny*
21 *a petition under this subsection, no further pe-*
22 *tition for such rule, submitted by the same per-*
23 *son, shall be considered by any agency unless*
24 *such petition is based on a change in a fact,*
25 *circumstance, or provision of law underlying*

1 *or otherwise related to the rule occurring since*
2 *the initial petition was granted or denied, that*
3 *warrants the granting of such further petition.*

4 *“§ 624. Decisional criteria*

5 *“(a) The requirements of this section shall*
6 *supplement any other decisional criteria oth-*
7 *erwise provided by law.*

8 *“(b) Subject to subsection (c), no final rule*
9 *subject to this subchapter shall be promul-*
10 *gated unless the agency finds that—*

11 *“(1) the potential benefits from the*
12 *rule justify the potential costs of the rule;*
13 *and*

14 *“(2) the rule will produce the most*
15 *cost-effective result of any of the reason-*
16 *able alternatives that the agency has dis-*
17 *cretion to adopt under the decisional cri-*
18 *teria of the statute granting the rule-*
19 *making authority.*

20 *“(c) If a statute requires or permits that a*
21 *rule be promulgated and that rule cannot, ap-*
22 *plying the express decisional criteria in the*
23 *statute, satisfy the criteria provided in sub-*
24 *section (b), the agency shall not promulgate*
25 *the rule unless the rule imposes—*

1 ***“(1) lower costs than any of the rea-***
2 ***sonable alternatives; or***

3 ***“(2) the least costs taking into account***
4 ***benefits that the agency has discretion to***
5 ***adopt under the decisional criteria of the***
6 ***statute granting the rulemaking author-***
7 ***ity.***

8 ***“(d) If an agency promulgates a rule that***
9 ***is subject to subsection (c), the agency shall***
10 ***prepare a written explanation of why the***
11 ***agency was required to promulgate a rule with***
12 ***potential costs that were not justified by the***
13 ***potential benefits and shall transmit that ex-***
14 ***planation along with the final cost-benefit***
15 ***analysis to Congress when the final rule is pro-***
16 ***mulgated.***

17 ***“§625. Judicial review***

18 ***“(a) Each court with jurisdiction to review***
19 ***final agency action under the statute granting***
20 ***the agency authority to conduct the rule-***
21 ***making shall have jurisdiction to review final***
22 ***agency action under this subchapter.***

23 ***“(b)(1) Any cost-benefit analysis of, or risk***
24 ***assessment concerning, a rule shall constitute***
25 ***part of the whole rulemaking record of agency***

1 *action for the purpose of judicial review and*
2 *shall be considered by a court in determining*
3 *the legality of the agency action, but only to*
4 *the extent that it relates to the agency's*
5 *decisional responsibilities under section 624*
6 *or the statute granting the agency authority to*
7 *take the agency action.*

8 “(2) *No analysis required by this sub-*
9 *chapter shall be subject to judicial review sep-*
10 *arate or apart from judicial review of the*
11 *agency action to which it relates.*

12 “(3) *The court shall apply the same stand-*
13 *ards of judicial review that govern the review*
14 *of agency findings under the statute granting*
15 *the agency authority to take the action.*

16 “(4) *The court shall set aside agency ac-*
17 *tion that fails to satisfy the decisional criteria*
18 *of section 624, applying the applicable judicial*
19 *review standards.*

20 “§ 626. *Deadlines for rulemaking*

21 “(a) *Beginning on the date of enactment of*
22 *this section, all deadlines in statutes that re-*
23 *quire agencies to propose or promulgate any*
24 *rule subject to this subchapter shall be sus-*

1 *pended until such time as the requirements of*
2 *this subchapter are satisfied.*

3 *“(b) Beginning on the date of enactment of*
4 *this section, the jurisdiction of any court of the*
5 *United States to enforce any deadline that*
6 *would require an agency to propose or promul-*
7 *gate a rule subject to this chapter shall be sus-*
8 *pended until such time as the requirements of*
9 *this subchapter are satisfied.*

10 *“(c) In any case in which the failure to pro-*
11 *mulgate a rule by a deadline would create an*
12 *obligation to regulate through individual ad-*
13 *judications by another deadline, the deadline*
14 *for such regulation shall be suspended to*
15 *allow the requirements of this subchapter to be*
16 *satisfied.*

17 *“§ 627. Agency review of rules*

18 *“(a)(1)(A) Not later than 9 months after*
19 *the date of enactment of this section, each*
20 *agency shall prepare and publish in the Fed-*
21 *eral Register a proposed schedule for the re-*
22 *view, in accordance with this section, of—*

23 *“(i) each rule of the agency that is in*
24 *effect on such effective date and which,*

1 *considering its future impact, would be a*
2 *major rule under this subchapter;*

3 “(ii) *each rule of the agency that is in-*
4 *consistent or incompatible with, or dupli-*
5 *cative of, any other obligation or require-*
6 *ment established by any Federal statute,*
7 *rule, or other agency statement, interpre-*
8 *tation, or action that has the force of law;*
9 *and*

10 “(iii) *each rule of the agency in effect*
11 *on the date of enactment of this section*
12 *(in addition to the rules described in*
13 *clauses (i) and (ii)) that the agency has*
14 *selected for review.*

15 “(B) *Each proposed schedule required by*
16 *subparagraph (A) shall include—*

17 “(i) *a brief explanation of the reasons*
18 *the agency considers each rule on the*
19 *schedule to be a major rule under section*
20 *621(4)(A), or the reasons why the agency*
21 *selected the rule for review;*

22 “(ii) *a date set by the agency, in ac-*
23 *cordance with subsection (b)(1), for the*
24 *completion of the review of each such*
25 *rule; and*

1 ***“(iii) a statement that the agency re-***
2 ***quests comments from the public on the***
3 ***proposed schedule.***

4 ***“(C) The agency shall set a date to initiate***
5 ***review of each rule on the schedule in a man-***
6 ***ner that will ensure the simultaneous review***
7 ***of related items and that will achieve a rea-***
8 ***sonable distribution of reviews over the period***
9 ***of time covered by the schedule.***

10 ***“(2) Not later than 90 days before publish-***
11 ***ing in the Federal Register the proposed sched-***
12 ***ule required under paragraph (1), each agen-***
13 ***cy shall make the proposed schedule available***
14 ***to the Director or a designee of the President,***
15 ***or to the Vice President or other officer to***
16 ***whom oversight authority has been delegated***
17 ***under section 643. The President or that offi-***
18 ***cer may select for review in accordance with***
19 ***this section any additional rule.***

20 ***“(3) Not later than 1 year after the date of***
21 ***enactment of this section, each agency shall***
22 ***publish in the Federal Register a final sched-***
23 ***ule for the review of the rules referred to in***
24 ***paragraphs (1) and (2). Each agency shall***
25 ***publish with the final schedule the response of***

1 *the agency to comments received concerning*
2 *the proposed schedule.*

3 *“(b)(1) Except as explicitly provided other-*
4 *wise by statute, the agency shall, pursuant to*
5 *subsections (c) through (e), review—*

6 *“(A) each rule on the schedule pro-*
7 *mulgated pursuant to subsection (a);*

8 *“(B) each major rule under section*
9 *621(4) promulgated, amended, or other-*
10 *wise renewed by an agency after the date*
11 *of the enactment of this section; and*

12 *“(C) each rule promulgated after the*
13 *date of enactment of this section that the*
14 *President or the officer designated by the*
15 *President selects for review pursuant to*
16 *subsection (a)(2).*

17 *“(2) Except as provided in subsection (f)—*

18 *“(A) in the case of a regulation that*
19 *takes effect after the date of enactment of*
20 *this section, the regulation shall termi-*
21 *nate on the date that is 5 years after the*
22 *date on which the regulation takes effect,*
23 *unless the review required by this section*
24 *has been completed by the date that is 5*

1 *years after the date on which the regula-*
2 *tion takes effect; and*

3 *“(B) in the case of a regulation in ef-*
4 *fect on the date of enactment of this sec-*
5 *tion, the regulation shall terminate on the*
6 *date that is 7 years after the date of en-*
7 *actment of the Regulatory Reform Act of*
8 *1995, unless the review required by this*
9 *section has been completed by the date*
10 *that is 7 years after the date of enactment*
11 *of the Regulatory Reform Act of 1995.*

12 *“(c) An agency shall publish in the Federal*
13 *Register a notice of its proposed action under*
14 *this section with respect to a rule being re-*
15 *viewed. The notice shall include—*

16 *“(1) an identification of the specific*
17 *statutory authority under which the rule*
18 *was promulgated and an explanation of*
19 *whether the agency’s interpretation of the*
20 *statute is expressly required by the cur-*
21 *rent text of that statute or, if not, an ex-*
22 *planation that the interpretation is with-*
23 *in the range of permissible interpretations*
24 *of the statute as identified by the agency,*
25 *and an explanation why the interpreta-*

1 ***tion selected by the agency is the agency's***
2 ***preferred interpretation;***

3 ***“(2) an analysis of the benefits and***
4 ***costs of the rule during the period in***
5 ***which it has been in effect;***

6 ***“(3) an explanation of the proposed***
7 ***agency action with respect to the rule, in-***
8 ***cluding action to repeal or amend the***
9 ***rule to resolve inconsistencies or conflicts***
10 ***with any other obligation or requirement***
11 ***established by any Federal statute, rule,***
12 ***or other agency statement, interpretation,***
13 ***or action that has the force of law; and***

14 ***“(4) a statement that the agency seeks***
15 ***proposals from the public for modifica-***
16 ***tions or alternatives to the rule which***
17 ***may accomplish the objectives of the rule***
18 ***in a more effective or less burdensome***
19 ***manner.***

20 ***“(d) If an agency proposes to repeal or***
21 ***amend a rule under review pursuant to this***
22 ***section, the agency shall, after issuing the no-***
23 ***tice required by subsection (c), comply with the***
24 ***provisions of this chapter, chapter 5, and any***
25 ***other applicable law. The requirements of***

1 *such provisions and related requirements*
2 *shall apply to the same extent and in the same*
3 *manner as in the case of a proposed agency ac-*
4 *tion to repeal or amend a rule that is not*
5 *taken pursuant to the review required by this*
6 *section.*

7 *“(e) If an agency proposes to renew without*
8 *amendment a rule under review pursuant to*
9 *this section, the agency shall—*

10 *“(1) give interested persons not less*
11 *than 60 days after the publication of the*
12 *notice required by subsection (c) to com-*
13 *ment on the proposed renewal; and*

14 *“(2) publish in the Federal Register*
15 *notice of the renewal of such rule, an ex-*
16 *planation of the continued need for the*
17 *rule, and, if the renewed rule is a major*
18 *rule under section 621(4), an explanation*
19 *of how the rule complies with section 624.*

20 *“(f) Any agency, which for good cause finds*
21 *that compliance with this section with respect*
22 *to a particular rule during the period pro-*
23 *vided in subsection (b) is contrary to an impor-*
24 *tant public interest, may request the President,*
25 *or an officer designated by the President, to es-*

1 *tablish a period longer than 5 years, in the*
2 *case of a regulation that takes effect after the*
3 *date of enactment of this section, or 7 years,*
4 *in the case of a regulation in effect on the date*
5 *of enactment of this section, for the completion*
6 *of the review of such rule. The President or*
7 *that officer may extend the period for review*
8 *of a rule to a total period of not more than 10*
9 *years. Such extension shall be published in the*
10 *Federal Register with an explanation of the*
11 *reasons therefor.*

12 “(g) *In any case in which an agency has*
13 *not completed the review of a rule within the*
14 *period prescribed by subsection (b) or (f) of*
15 *this section, the agency shall immediately pub-*
16 *lish in the Federal Register a notice proposing*
17 *to issue the rule under subsection (c), and*
18 *shall complete proceedings pursuant to sub-*
19 *section (d) or (e) not later than 180 days after*
20 *the date on which the review was required to*
21 *be completed under subsection (b) or (f).*

22 “(h) *Nothing in this section shall relieve*
23 *any agency from its obligation to respond to a*
24 *petition to issue, amend, or repeal a rule, for*
25 *an interpretation regarding the meaning of a*

1 *rule, or for a variance or exemption from the*
 2 *terms of a rule, submitted pursuant to any*
 3 *other provision of law.*

4 *“§628. Special rule*

5 *“Notwithstanding any other provision of*
 6 *the Comprehensive Regulatory Reform Act of*
 7 *1995, or the amendments made by such Act, for*
 8 *purposes of this subchapter and subchapter*
 9 *IV, the head of each appropriate Federal*
 10 *banking agency (as defined in section 3(q) of*
 11 *the Federal Deposit Insurance Act), the Na-*
 12 *tional Credit Union Administration, the Fed-*
 13 *eral Housing Finance Board, the Office of Fed-*
 14 *eral Housing Enterprise Oversight, and the*
 15 *Farm Credit Administration, shall have au-*
 16 *thority with respect to such agency that other-*
 17 *wise would be provided under such sub-*
 18 *chapters to the Director, a designee of the*
 19 *President, Vice President, or any officer des-*
 20 *ignated or delegated with authority under*
 21 *such subchapters.*

22 *“SUBCHAPTER III—RISK ASSESSMENTS*

23 *“§631. Definitions*

24 *“For purposes of this subchapter—*

1 ***“(1) the term ‘benefit’ has the meaning***
2 ***given such term in section 621(1);***

3 ***“(2) the term ‘best estimate’ means an***
4 ***estimate that, to the extent feasible and***
5 ***scientifically appropriate, is based on—***

6 ***“(A) central estimates of risk***
7 ***using the most plausible and realistic***
8 ***assumptions;***

9 ***“(B) an approach that combines***
10 ***multiple estimates based on different***
11 ***scenarios and weighs the probability***
12 ***of each scenario; and***

13 ***“(C) any other methodology de-***
14 ***signed to provide the most plausible***
15 ***and realistic level of risk, given the***
16 ***current scientific information avail-***
17 ***able to the agency concerned;***

18 ***“(3) the term ‘cost’ has the meaning***
19 ***given such term in section 621(2);***

20 ***“(4) the term ‘cost-benefit analysis’***
21 ***has the meaning given such term in sec-***
22 ***tion 621(3);***

23 ***“(5) the term ‘emergency’ means an ac-***
24 ***tual, immediate, and substantial***

1 *endangerment to health, safety, or the*
2 *human environment;*

3 “(6) the term ‘hazard identification’
4 *means identification of a substance, activ-*
5 *ity, or condition that may cause to health,*
6 *safety, or the environment based on empir-*
7 *ical data, measurements, or testing show-*
8 *ing that it has caused significant adverse*
9 *effects at some levels of dose or exposure*
10 *combined degree of toxicity and actual ex-*
11 *posure, or other risk the hazards pose for*
12 *individuals, populations, or natural re-*
13 *sources; and*

14 “(7) the term ‘major cleanup plan’
15 *means any proposed or final environ-*
16 *mental cleanup plan for a facility, or Fed-*
17 *eral guidelines for the issuance of any*
18 *such plan, the expected costs, expenses,*
19 *and damages of which are likely to ex-*
20 *ceed, in the aggregate, \$10,000,000, includ-*
21 *ing a corrective action requirement under*
22 *the Solid Waste Disposal Act (notwith-*
23 *standing section 4(b)(1)(C) of such Act,*
24 *but only to the extent of such require-*
25 *ment), a removal or remedial action*

1 *under the Comprehensive Environmental*
2 *Response, Compensation, and Liability*
3 *Act of 1980, and any other environmental*
4 *restoration or damage assessment carried*
5 *out by, on behalf of, or as required or or-*
6 *dered by, an agency or Federal court, or*
7 *pursuant to the authority of a Federal*
8 *statute with respect to any substance;*

9 *“(8) the term ‘major rule’ has the*
10 *meaning given such term in section*
11 *621(4);*

12 *“(9) the term ‘negative data’ means*
13 *data that fail to show that a given sub-*
14 *stance or activity induces an adverse ef-*
15 *fect under certain conditions;*

16 *“(10) the term ‘risk assessment’*
17 *means—*

18 *“(A) the process of identifying haz-*
19 *ards, and of quantifying (to the maxi-*
20 *imum extent practicable) or describing*
21 *the combined degree of toxicity and*
22 *actual exposure, or other risk the haz-*
23 *ards pose for individuals, popu-*
24 *lations, or natural resources; and*

1 ***“(B) the document containing the***
2 ***explanation of how the assessment***
3 ***process has been applied to an indi-***
4 ***vidual substance, activity, or condi-***
5 ***tion;***

6 ***“(11) the term ‘risk characteriza-***
7 ***tion’—***

8 ***“(A) means the element of a risk***
9 ***assessment that involves presentation***
10 ***of the degree of risk to individuals***
11 ***and populations expected to be pro-***
12 ***ected, as presented in any regulatory***
13 ***proposal or decision, report to Con-***
14 ***gress, or other document that is made***
15 ***available to the public; and***

16 ***“(B) may include discussions of***
17 ***uncertainties, conflicting data, esti-***
18 ***mates, extrapolations, inferences, and***
19 ***opinions, as appropriate;***

20 ***“(12) the term ‘rule’ has the meaning***
21 ***given such term in section 621(7); and***

22 ***“(13) the term ‘substitution risk’***
23 ***means a potential increased risk to***
24 ***health, safety, or the environment result-***
25 ***ing from market substitutions, a reduced***

1 *standard of living, or a regulatory alter-*
2 *native designed to decrease other risks.*

3 ***“§632. Applicability***

4 ***“(a) Except as provided in subsection (b),***
5 ***this subchapter shall apply to all risk assess-***
6 ***ments and risk characterizations prepared by,***
7 ***or on behalf of, or prepared by others and***
8 ***adopted by, any agency in connection with***
9 ***health, safety, and environmental risks.***

10 ***“(b)(1) This subchapter shall not apply to***
11 ***risk assessments or risk characterizations per-***
12 ***formed with respect to—***

13 ***“(A) a situation that the head of the***
14 ***agency finds to be an emergency;***

15 ***“(B) a rule or agency action that au-***
16 ***thorizes the introduction into or removal***
17 ***from commerce, or initiation of manufac-***
18 ***ture, of a substance, mixture, or product,***
19 ***or recognizes the marketable status of a***
20 ***product;***

21 ***“(C) a health, safety, or environmental***
22 ***inspection, compliance or enforcement ac-***
23 ***tion, or individual facility permitting ac-***
24 ***tion; or***

1 ***“(D) a screening analysis clearly identified as such.***
2

3 ***“(2)(A) An analysis shall not be treated as***
4 ***a screening analysis for the purposes of para-***
5 ***graph (1)(D) if the result of the analysis is***
6 ***used—***

7 ***“(i) as the basis for imposing a restric-***
8 ***tion on a previously authorized substance,***
9 ***product, or activity after its initial intro-***
10 ***duction into manufacture or commerce; or***

11 ***“(ii) to characterize a finding of risk***
12 ***from a substance or activity in any agency***
13 ***document or other communication made***
14 ***available to the public, the media, or Con-***
15 ***gress.***

16 ***“(B) Among the analyses that may be treat-***
17 ***ed as a screening analyses for the purposes of***
18 ***paragraph (1)(D) are product registrations,***
19 ***reregistrations, tolerance settings, and reviews***
20 ***of premanufacture notices under the Federal***
21 ***Insecticide, Fungicide, and Rodenticide Act (7***
22 ***U.S.C. 136 et seq.) and the Toxic Substances***
23 ***Control Act (15 U.S.C. 2601 et seq.).***

24 ***“(3) This subchapter shall not apply to any***
25 ***food, drug, or other product label or to any***

1 *risk characterization appearing on any such*
2 *label.*

3 *“§ 633. Principles for risk assessment*

4 *“(a)(1) The head of each agency shall*
5 *apply the principles set forth in subsection (b)*
6 *when preparing any risk assessment for a*
7 *major rule to ensure that the risk assessment*
8 *and all of its components—*

9 *“(A) distinguish scientific findings*
10 *and best estimates of risk from other con-*
11 *siderations;*

12 *“(B) are, to the maximum extent prac-*
13 *ticable, scientifically objective, plausible,*
14 *and realistic, and inclusive of all relevant*
15 *data;*

16 *“(C) rely, to the extent available and*
17 *practicable, on scientific findings; and*

18 *“(D) use situation- or decision-specific*
19 *information to the maximum extent prac-*
20 *ticable.*

21 *“(2) An agency shall not be required to re-*
22 *peat discussions or explanations required*
23 *under this section in each risk assessment doc-*
24 *ument if there is an unambiguous reference to*
25 *the relevant discussion or explanation in an-*

1 *other reasonably available agency document*
2 *that was prepared in accordance with this*
3 *subchapter.*

4 *“(b) The principles to be applied when pre-*
5 *paring risk assessments are as follows:*

6 *“(1)(A) When assessing human health*
7 *risks, a risk assessment shall consider*
8 *and discuss both the most important lab-*
9 *oratory and epidemiological data, includ-*
10 *ing negative data, and summarize the re-*
11 *maining data that finds, or fails to find,*
12 *a correlation between a health risk and a*
13 *substance or activity.*

14 *“(B) When conflicts among such data*
15 *appear to exist, or when animal data are*
16 *used as a basis to assess human health,*
17 *the assessment shall include a discussion*
18 *of possible reconciliation of conflicting in-*
19 *formation. Greatest emphasis shall be*
20 *placed on data that indicates the biologi-*
21 *cal basis of the resulting harm in hu-*
22 *mans. Animal data shall be reviewed with*
23 *regard to relevancy to humans.*

24 *“(2) When a risk assessment involves a*
25 *choice of any significant assumption (in-*

1 *cluding the use of safety factors and de-*
2 *fault assumptions), inference, or model,*
3 *the agencies or instrumentality preparing*
4 *the assessment shall—*

5 *“(A) present a representative de-*
6 *scription and explicit explanation of*
7 *plausible and alternative similar as-*
8 *sumptions, inferences, or models (in-*
9 *cluding the assumptions incorporated*
10 *into the model) and the sensitivity of*
11 *the conclusions to them;*

12 *“(B) give preference to the model,*
13 *assumption, input parameter that rep-*
14 *resents the most plausible or realistic*
15 *inference from supporting scientific*
16 *information;*

17 *“(C) identify any science policy or*
18 *value judgments and employ those*
19 *judgments only where the policy deter-*
20 *mination has been approved by the*
21 *head of the agency, after notice and*
22 *opportunity for public involvement, as*
23 *appropriate for the circumstance*
24 *under consideration;*

1 ***“(D) describe any model used in***
2 ***the risk-assessment and make explicit***
3 ***the assumptions incorporated into the***
4 ***model; and***

5 ***“(E) indicate the extent to which***
6 ***any significant model has been vali-***
7 ***dated by, or conflicts with, empirical***
8 ***data.***

9 ***“(3) Risk assessments that provide a***
10 ***quantification or numerical output shall***
11 ***be calculated using the best estimate for***
12 ***each input parameter and shall use, as***
13 ***available, probabilistic descriptions of the***
14 ***uncertainty and variability associated***
15 ***with each input parameter.***

16 ***“(4) A risk assessment shall clearly***
17 ***separate hazard identification from risk***
18 ***characterization and make clear the rela-***
19 ***tionship between the level of risk and the***
20 ***level of exposure to a potential hazard.***

21 ***“(5) A risk assessment shall be pre-***
22 ***pared at the level of detail appropriate***
23 ***and practicable for reasoned decision-***
24 ***making on the matter involved, taking***
25 ***into consideration the significance and***

1 ***complexity of the decision and any need***
2 ***for expedition.***

3 ***“(6) Where relevant, practicable, and***
4 ***appropriate, data shall be developed con-***
5 ***sistent with standards for the develop-***
6 ***ment of test data promulgated pursuant***
7 ***to section 4 of the Toxic Substances Con-***
8 ***trol Act, and standards for data require-***
9 ***ments promulgated pursuant to section 3***
10 ***of the Federal Insecticide, Fungicide, and***
11 ***Rodenticide Act.***

12 ***“(c)(1) The head of each agency shall pro-***
13 ***mote early involvement by all stakeholders in***
14 ***the development of risk assessments that may***
15 ***support or affect agency rules, guidance, and***
16 ***other significant actions, by publishing as***
17 ***part of its semiannual regulatory agenda, re-***
18 ***quired under section 602—***

19 ***“(A) a list of risk assessments and***
20 ***supporting assessments, including haz-***
21 ***ard, dose or exposure assessments, under***
22 ***preparation or planned by the agency;***

23 ***“(B) a brief summary of relevant is-***
24 ***sues addressed or to be addressed by each***

1 *listed risk assessment or supporting as-*
2 *essment;*

3 *“(C) an approximate schedule for com-*
4 *pleting each listed risk assessment and*
5 *supporting assessment;*

6 *“(D) an identification of potential*
7 *rules, guidance, or other agency actions*
8 *supported or affected by each listed risk*
9 *assessment and supporting assessment;*
10 *and*

11 *“(E) the name, address, and telephone*
12 *number of an agency official knowledge-*
13 *able about each listed risk assessment*
14 *and supporting assessment.*

15 *“(2)(A) The head of each agency shall pro-*
16 *vide an opportunity for meaningful public*
17 *participation and comment on any risk assess-*
18 *ment throughout the regulatory process com-*
19 *mensurate with the consequences of the deci-*
20 *sion to be made.*

21 *“(B) In cases where the risk assessment*
22 *will support a major rule, the agency shall*
23 *publish, at the earliest opportunity in the*
24 *process, an advanced notice of relevant risk*

1 *assessment related information that includes,*
2 *at a minimum, an identification of—*

3 *“(i) all relevant hazard, dose, expo-*
4 *sure, and other risk related documents*
5 *that the agency plans to consider;*

6 *“(ii) all risk related guidance that the*
7 *agency considers relevant;*

8 *“(iii) all hazard, dose, exposure, and*
9 *other risk assumptions on which the agen-*
10 *cy plans to relay and the bases therefor;*
11 *and*

12 *“(iv) all data and information defi-*
13 *ciencies that could affect agency decision-*
14 *making.*

15 *“(d)(1) No agency shall automatically in-*
16 *corporate or adopt any recommendation or*
17 *classification made by an entity described in*
18 *paragraph (2) concerning the health effects or*
19 *value of a substance without an opportunity*
20 *for notice and comment. Any risk assessment*
21 *or risk characterization document adopted by*
22 *an agency on the basis of such a recommenda-*
23 *tion or classification shall comply with this*
24 *title.*

1 ***“(2) An entity referred to in paragraph (1)***
2 ***includes—***

3 ***“(A) any foreign government and its***
4 ***agencies;***

5 ***“(B) the United Nations or any of its***
6 ***subsidiary organizations;***

7 ***“(C) any international governmental***
8 ***body or standards-making organization;***
9 ***and***

10 ***“(D) any other organization or private***
11 ***entity without that does not have a place***
12 ***of business located in the United States or***
13 ***its territories.***

14 ***“§ 634. Principles for risk characterization and com-***
15 ***munication***

16 ***“In characterizing risk in any risk assess-***
17 ***ment document, regulatory proposal or deci-***
18 ***sion, report to Congress, or other document re-***
19 ***lating in each case to a major rule that is***
20 ***made available to the public, each agency***
21 ***characterizing the risk shall comply with each***
22 ***of the following:***

23 ***“(1) The head of the agency shall de-***
24 ***scribe the exposure scenarios used in any***
25 ***risk assessment, and, to the extent fea-***

1 *sible, provide an estimate of the size of the*
2 *corresponding population or natural re-*
3 *source at risk and the likelihood of such*
4 *exposure scenarios.*

5 *“(2) If a numerical estimate of risk is*
6 *provided, the head of the agency, to the*
7 *extent feasible and scientifically appro-*
8 *priate, shall provide—*

9 *“(A) the range and distribution of*
10 *exposures derived from exposure sce-*
11 *narios used in a risk assessment, in-*
12 *cluding, where appropriate, central*
13 *and high-end estimates, but always*
14 *including a best estimate of the risk to*
15 *the general population;*

16 *“(B) the range and distribution of*
17 *risk estimates, including best esti-*
18 *mates and, where quantitative esti-*
19 *mates of the range of distribution of*
20 *risk estimates are not possible, a list*
21 *of qualitative factors influencing the*
22 *range of possible risks; and*

23 *“(C) a statement of the major*
24 *sources of uncertainties in the hazard*
25 *identification, dose-response, and ex-*

1 ***posure assessment phases of risk as-***
2 ***essment and their influence on the***
3 ***results of the assessment.***

4 ***“(3) To the extent feasible, the head of***
5 ***the agency shall provide a statement that***
6 ***places the nature and magnitude of indi-***
7 ***vidual and population risks to human***
8 ***health in context.***

9 ***“(4) When a Federal agency provides a***
10 ***risk assessment or risk characterization***
11 ***for a proposed or final regulatory action,***
12 ***such assessment or characterization shall***
13 ***include a statement of any significant***
14 ***substitution risks to human health identi-***
15 ***fied by the agency or contained in infor-***
16 ***mation provided to the agency by a com-***
17 ***mentator.***

18 ***“(5) An agency shall present a sum-***
19 ***mary in connection with the presentation***
20 ***of the agency’s risk assessment or the reg-***
21 ***ulation if—***

22 ***“(A) the agency provides a public***
23 ***comment period with respect to a risk***
24 ***assessment or regulation;***

1 ***“(B) a commentator provides a***
2 ***risk assessment, and a summary of re-***
3 ***sults of such risk assessment; and***

4 ***“(C) such risk assessment is rea-***
5 ***sonably consistent with the principles***
6 ***and the guidance provided under this***
7 ***subtitle.***

8 ***“§ 635. Requirement to prepare assessment***

9 ***“(a) Except as provided in section 632 and***
10 ***in addition to any requirements applicable***
11 ***under subchapter II, the head of each agency***
12 ***shall prepare—***

13 ***“(1) for each major rule relating to***
14 ***health, safety, or the environment, and for***
15 ***each major cleanup plan, that is proposed***
16 ***by the agency after the date of enactment***
17 ***of this subchapter, is pending on the date***
18 ***of enactment of this subchapter, or is sub-***
19 ***ject to a granted petition for review pur-***
20 ***suant to section 553(e) or 623, a risk as-***
21 ***essment in accordance with this sub-***
22 ***chapter;***

23 ***“(2) for each such proposed or final***
24 ***plan, and each reasonable alternative***
25 ***within the statutory authority of the agen-***

1 *cy taking action, a cost-benefit analysis*
2 *equivalent to that which would be re-*
3 *quired under subchapter II if subchapter*
4 *II were applicable; and*

5 *“(3) for each such proposed or final*
6 *plan, quantified to the extent feasible, a*
7 *comparison of any health, safety, or envi-*
8 *ronmental risks addressed by the regu-*
9 *latory alternatives to other relevant risks*
10 *chosen by the head of the agency, includ-*
11 *ing at least 3 other risks regulated by the*
12 *agency and to at least 3 other risks with*
13 *which the public is familiar.*

14 *“(b) A major cleanup plan is subject to this*
15 *subchapter if—*

16 *“(1) construction has not commenced*
17 *on a significant portion of the work re-*
18 *quired by the plan; or*

19 *“(2) if construction has commenced on*
20 *a significant portion of the work required*
21 *by the plan, unless—*

22 *“(A) it is more cost-effective to*
23 *complete construction of the work*
24 *than to apply the provisions of this*
25 *subchapter; or*

1 ***“(B) the application of the provi-***
2 ***sions of this subchapter, including***
3 ***any delays caused thereby, will result***
4 ***in an actual and immediate risk to***
5 ***human health or welfare.***

6 ***“(c) A risk assessment prepared pursuant***
7 ***to this subchapter shall be a component of and***
8 ***used to develop any cost-benefit analysis re-***
9 ***quired by this subchapter or subchapter II,***
10 ***and shall, along with any cost-benefit analysis***
11 ***required by this subchapter, be made part of***
12 ***the administrative record for judicial review***
13 ***of any final agency action.***

14 ***“§ 636. Requirements for assessments***

15 ***“(a) The head of the agency, subject to re-***
16 ***view by the Director or a designee of the Presi-***
17 ***dent, shall make a determination that, not-***
18 ***withstanding any other provision of law—***

19 ***“(1) for each major rule and major***
20 ***cleanup plan subject to this subchapter,***
21 ***the risk assessment required under sec-***
22 ***tion 635 is based on a scientific, plausible,***
23 ***and realistic evaluation, reflecting rea-***
24 ***sonable exposure scenarios, of the risk ad-***
25 ***dressed by the major rule and is sup-***

1 *ported by the best available scientific*
2 *data, as determined by a peer review*
3 *panel in accordance with section 640; and*

4 *“(2) for each major cleanup plan sub-*
5 *ject to this subchapter, the plan has bene-*
6 *fits that justify its costs and that there is*
7 *no alternative that is allowed by the stat-*
8 *ute under which the plan is promulgated*
9 *that would provide greater net benefits or*
10 *that would achieve an equivalent reduc-*
11 *tion in risk in a more cost-effective and*
12 *flexible manner.*

13 *“(b) Notwithstanding any other provision*
14 *of law, no agency shall prohibit or refuse to*
15 *approve a substance or product on the basis of*
16 *safety where the substance or product presents*
17 *a negligible or insignificant human risk under*
18 *the intended conditions of use.*

19 *“(c) Notwithstanding any other provision*
20 *of law, issuance of a record of decision or a*
21 *final permit condition or administrative order*
22 *containing a major cleanup plan, or denial of,*
23 *or completion of agency review pursuant to, a*
24 *petition for review of a major cleanup plan*
25 *under section 637(c), shall constitute final*

1 *agency action subject to judicial review at the*
2 *time this action is taken.*

3 *“§637. Regulations; plan for assessing new informa-*
4 *tion*

5 *“(a)(1) Not later than 1 year after the date*
6 *of enactment of this subchapter, the Director*
7 *or a designee of the President shall—*

8 *“(A) issue a final regulation that has*
9 *been subject to notice and comment under*
10 *section 553 that directs agencies to imple-*
11 *ment the risk assessment and risk charac-*
12 *terization principles set forth in sections*
13 *633 and 634; and*

14 *“(B) provide a format for summariz-*
15 *ing risk assessment results.*

16 *“(2) The regulation under paragraph (1)*
17 *shall be sufficiently specific to ensure that risk*
18 *assessments are conducted consistently by the*
19 *various agencies.*

20 *“(b) Review of a risk assessment or any*
21 *entry (or the evaluation underlying the entry)*
22 *on an agency-developed database (including,*
23 *but not limited to, the Integrated Risk Infor-*
24 *mation System), shall be conducted by the*
25 *head of the agency on the written petition of*

1 ***a person showing a reasonable likelihood***
2 ***that—***

3 ***“(1) the risk assessment or entry is in-***
4 ***consistent with the principles set forth in***
5 ***sections 633 and 634;***

6 ***“(2) the risk assessment or entry con-***
7 ***tains different results than if it had been***
8 ***properly conducted under sections 633***
9 ***and 634;***

10 ***“(3) the risk assessment or entry is in-***
11 ***consistent with a rule issued under sub-***
12 ***section (a); or***

13 ***“(4) the risk assessment or entry does***
14 ***not take into account material significant***
15 ***new scientific data or scientific under-***
16 ***standing.***

17 ***“(c) Review of a risk assessment, a cost-***
18 ***benefit analysis, or both, for a major cleanup***
19 ***plan shall be conducted by the head of the***
20 ***agency on the written petition of a person***
21 ***showing a reasonable likelihood that—***

22 ***“(1) the risk assessment warrants revi-***
23 ***sion under any of the criteria set forth in***
24 ***subsection (b); or***

1 ***“(2) the cost-benefit analysis warrants***
2 ***revision under any of the criteria set forth***
3 ***in section 624.***

4 ***“(d)(1) Not later than 90 days after receiv-***
5 ***ing a petition under subsection (b), the head***
6 ***of the agency shall respond to the petition by***
7 ***agreeing or declining to review the risk entry,***
8 ***the cost-benefit analysis, or both, referred to in***
9 ***the petition, and shall state the basis for the***
10 ***decision.***

11 ***“(2) If the head of the agency agrees to re-***
12 ***view the petition, the agency shall complete its***
13 ***review not later than 180 days after the deci-***
14 ***sion made under paragraph (1), unless the Di-***
15 ***rector agrees in writing with an agency deter-***
16 ***mination that an extension is necessary in***
17 ***view of limitations on agency resources. Prior***
18 ***to completion of the agency review, the agen-***
19 ***cy’s written conclusions concerning the review***
20 ***shall be subjected to peer review pursuant to***
21 ***section 640.***

22 ***“(3) A risk assessment review completed***
23 ***pursuant to a petition may be the basis for ini-***
24 ***tiating a petition pursuant to any other provi-***
25 ***sion of law.***

1 ***“(4) Following a decision to grant or deny***
2 ***a petition under subsection (b) or (c), no fur-***
3 ***ther petition for such risk assessment, entry, or***
4 ***cost-benefit analysis, submitted by the same***
5 ***person, shall be considered by any agency un-***
6 ***less such petition is based on a change in a***
7 ***fact, circumstance, or provision of law under-***
8 ***lying or otherwise related to the matters cov-***
9 ***ered by the initial petition, occurring since the***
10 ***initial petition was granted or denied, that***
11 ***warrants the granting of such further petition.***

12 ***“(e) The regulations under this section***
13 ***shall be developed after notice and oppor-***
14 ***tunity for public comment, and after consulta-***
15 ***tion with representatives of appropriate State***
16 ***agencies and local governments, and such***
17 ***other departments, agencies, offices, organiza-***
18 ***tions, or persons as may be advisable.***

19 ***“(f) At least every 4 years, the Director or***
20 ***a designee of the President shall review, and***
21 ***when appropriate, revise, the regulations pub-***
22 ***lished under this section.***

23 ***“§ 638. Rule of construction***

24 ***“Nothing in this subchapter shall be con-***
25 ***strued to—***

1 ***“(1) preclude the consideration of any***
2 ***data or the calculation of any estimate to***
3 ***more fully describe risk or provide exam-***
4 ***ples of scientific uncertainty or varia-***
5 ***bility; or***

6 ***“(2) require the disclosure of any***
7 ***trade secret or other confidential infor-***
8 ***mation.***

9 ***“§639. Regulatory priorities***

10 ***“(a)(1) Not later than 180 days after the***
11 ***date of enactment of this section, the Director***
12 ***of the Office of Management and Budget, in***
13 ***consultation with the Office of Science and***
14 ***Technology Policy, shall enter into appro-***
15 ***priate arrangements with an accredited sci-***
16 ***entific body to—***

17 ***“(A) conduct a study of the methodolo-***
18 ***gies for using comparative risk to rank***
19 ***dissimilar health, safety, and environ-***
20 ***mental risks; and***

21 ***“(B) to conduct a comparative risk***
22 ***analysis in accordance with paragraph***
23 ***(2).***

24 ***“(2) The study of the methodologies under***
25 ***paragraph (1)(A) shall be conducted as part of***

1 *the first comparative risk analysis under*
2 *paragraph (1)(B). The study shall—*

3 *“(A) seek to develop and rigorously*
4 *test methods of comparative risk analysis;*

5 *“(B) have sufficient scope and breadth*
6 *to test approaches for improving com-*
7 *parative risk analysis and its use in set-*
8 *ting priorities for health, safety, and envi-*
9 *ronmental risk prevention and reduction;*
10 *and*

11 *“(C) review and evaluate the experi-*
12 *ence of States that have conducted com-*
13 *parative risk analyses.*

14 *“(3)(A) The comparative risk analysis*
15 *under paragraph (1)(B) shall compare and*
16 *rank, to the extent feasible, health, safety, and*
17 *environmental risks potentially regulated*
18 *across the spectrum of programs relating to*
19 *health, safety, and the environment adminis-*
20 *tered by the departments, agencies, and instru-*
21 *mentalities of the Federal Government.*

22 *“(B) In carrying out the comparative risk*
23 *analysis under this paragraph, the Director*
24 *shall ensure that—*

1 “(i) the scope and specificity of the
2 analysis are sufficient to provide the
3 President and the heads of agencies guid-
4 ance in allocating resources across agen-
5 cies and among programs in agencies to
6 achieve the greatest degree of risk preven-
7 tion and reduction for the public and pri-
8 vate resources expended;

9 “(ii) the analysis is conducted through
10 an open process, by individuals with rel-
11 evant expertise, including, as appro-
12 priate—

13 “(I) toxicologists;

14 “(II) biologists;

15 “(III) engineers; and

16 “(IV) experts in the fields of medi-
17 cine, industrial hygiene, and environ-
18 mental effects;

19 “(iii) the analysis is conducted, to the
20 extent feasible, consistent with the risk as-
21 sessment and risk characterization prin-
22 ciples described in sections 633 and 634;

23 “(iv) the methodologies and principal
24 scientific determinations made in the
25 analysis are subjected to peer review

1 ***under section 640 and the conclusions of***
2 ***the peer review are made publicly avail-***
3 ***able as part of the final report;***

4 ***“(v) there is an opportunity for public***
5 ***comments on the results of the analysis***
6 ***prior to making them final; and***

7 ***“(vi) the results of the analysis are***
8 ***presented in a manner that distinguishes***
9 ***between the scientific conclusions and any***
10 ***policy or value judgments embodied in the***
11 ***comparisons.***

12 ***“(4) The comparative risk analysis shall be***
13 ***completed, and a report submitted to Congress***
14 ***not later than 3 years after the date of enact-***
15 ***ment of this section. The analysis shall be re-***
16 ***viewed and revised not less often than every 5***
17 ***years thereafter for a minimum of 15 years fol-***
18 ***lowing the release of the initial analysis.***

19 ***“(b) Not later than 180 days after the date***
20 ***of enactment of this section, the Director of the***
21 ***Office of Management and Budget, in collabo-***
22 ***ration with the head of each Federal agency,***
23 ***shall enter into a contract with the National***
24 ***Research Council to provide technical guid-***
25 ***ance to the agencies on approaches to using***

1 *comparative risk analysis in setting health,*
2 *safety, and environmental priorities to assist*
3 *the agencies in complying with subsection (c).*

4 *“(c)(1) In exercising authority under any*
5 *laws protecting health, safety, or the environ-*
6 *ment, the head of an agency shall prioritize*
7 *the use of the resources available under such*
8 *laws to address the risks to health, safety, and*
9 *the environment that—*

10 *“(A) the agency determines are the*
11 *most serious; and*

12 *“(B) can be addressed in a cost-effec-*
13 *tive manner, with the goal of achieving*
14 *the greatest overall net reduction in risks*
15 *with the public and private sector re-*
16 *sources to be expended.*

17 *“(2) In identifying the sources of the most*
18 *serious risks under paragraph (1), the head of*
19 *the agency shall consider, at a minimum—*

20 *“(A) the plausible likelihood and se-*
21 *verity of the effect; and*

22 *“(B) the plausible number and groups*
23 *of individuals potentially affected.*

24 *“(3) The head of the agency shall incor-*
25 *porate the priorities identified in paragraph*

1 ***(1) into the budget, strategic planning, and re-***
2 ***search activities of the agency by, in the agen-***
3 ***cy's annual budget request to Congress—***

4 ***“(A) identifying which risks the agen-***
5 ***cy has determined are the most serious***
6 ***and can be addressed in a cost-effective***
7 ***manner under paragraph (1), and the***
8 ***basis for that determination;***

9 ***“(B) explicitly identifying how the***
10 ***agency's requested funds will be used to***
11 ***address those risks;***

12 ***“(C) identifying any statutory, regu-***
13 ***latory, or administrative obstacles to allo-***
14 ***cating agency resources in accordance***
15 ***with the priorities established under***
16 ***paragraph (1); and***

17 ***“(D) explicitly considering the re-***
18 ***quirements of paragraph (1) when prepar-***
19 ***ing the agency's regulatory agenda or***
20 ***other strategic plan, and providing an ex-***
21 ***planation of how the agenda or plan re-***
22 ***fects those requirements and the com-***
23 ***parative risk analysis when publishing***
24 ***any such agenda or strategic plan.***

1 ***“(4) In March of each year, the head of***
2 ***each agency shall submit to Congress specific***
3 ***recommendations for repealing or modifying***
4 ***laws that would better enable the agency to***
5 ***prioritize its activities to address the risks to***
6 ***health, safety, and the environment that are***
7 ***the most serious and can be addressed in a***
8 ***cost-effective manner consistent with the re-***
9 ***quirements of paragraph (1).***

10 ***“§ 640. Establishment of program***

11 ***“(a) The Director of the Office of Science***
12 ***and Technology or the Director, as appro-***
13 ***priate, shall develop a systematic program for***
14 ***the peer review of work products covered by***
15 ***subsection (c), which program shall be used, in***
16 ***as uniform a manner as is practicable, across***
17 ***the agencies.***

18 ***“(b) The program under subsection (a)—***

19 ***“(1) shall provide for the creation of***
20 ***peer review panels consisting of independ-***
21 ***ent and external experts who are broadly***
22 ***representative and balanced to the extent***
23 ***feasible;***

24 ***“(2) shall not exclude peer reviewers***
25 ***merely because they represent entities that***

1 *may have a potential interest in the out-*
2 *come, if that interest is fully disclosed;*

3 *“(3) shall exclude experts who were*
4 *associated with the generation of the spe-*
5 *cific work product either directly by sub-*
6 *stantial contribution to its development,*
7 *or indirectly by consultation and develop-*
8 *ment of the specific product;*

9 *“(4) shall provide for differing levels*
10 *of peer review depending on the signifi-*
11 *cance or complexity of the issue or the*
12 *need for expedition;*

13 *“(5) shall contain balanced presen-*
14 *tations of all considerations, including*
15 *minority reports and an agency response*
16 *to all significant peer review comments;*
17 *and*

18 *“(6) shall provide an opportunity for*
19 *interested parties to submit issues for con-*
20 *sideration by peer review panels.*

21 *“(c) Matters requiring peer review shall in-*
22 *clude—*

23 *“(1) risk assessments and cost-benefit*
24 *analyses for major rules;*

1 ***“(2) quantitative estimates of risk or***
2 ***hazard that are used in making regu-***
3 ***latory determinations, including all en-***
4 ***tries into the Integrated Risk Information***
5 ***System;***

6 ***“(3) risk assessment and risk charac-***
7 ***terization regulations and cost-benefit***
8 ***guidelines; and***

9 ***“(4) any other significant or technical***
10 ***work product, as designated by the head***
11 ***of each agency, the Director of the Office***
12 ***of Science and Technology, or the Direc-***
13 ***tor.***

14 ***“(d) All underlying data shall be submit-***
15 ***ted to peer reviewers, except to the extent nec-***
16 ***essary to protect confidential business infor-***
17 ***mation and trade secrets. To ensure such pro-***
18 ***tections, the head of the agency may require***
19 ***that peer reviewers enter into confidentiality***
20 ***agreements.***

21 ***“(e) The peer review and the agency’s re-***
22 ***sponses shall be made available to the public***
23 ***for comment and the final peer review and the***
24 ***agency’s responses shall be made part of the***

1 *administrative record for purposes of judicial*
2 *review.*

3 *“(f) The proceedings of peer review panels*
4 *under this section shall be subject to the appli-*
5 *cable provisions of the Federal Advisory Com-*
6 *mittee Act.*

7 **“SUBCHAPTER IV—EXECUTIVE**
8 **OVERSIGHT**

9 **“§ 641. Procedures**

10 *“(a) The Director or a designee of the*
11 *President shall—*

12 *“(1) establish procedures for agency*
13 *compliance with this chapter; and*

14 *“(2) monitor, review, and ensure agen-*
15 *cy implementation of such procedures.*

16 *“(b) Not later than 12 months after the*
17 *date of enactment of this subchapter the Office*
18 *of Management and Budget shall issue regula-*
19 *tions to assist agencies in preparing the cost-*
20 *benefit analyses required by this subchapter.*
21 *The regulations shall—*

22 *“(1) ensure that cost and benefit eval-*
23 *uations are consistent with this sub-*
24 *chapter and, to the extent feasible, rep-*
25 *resent realistic and plausible estimates;*

1 “(2) *be adopted following public no-*
2 *tice and adequate opportunity for com-*
3 *ment; and*

4 “(3) *be used consistently by all agen-*
5 *cies covered by this subchapter.*

6 “§ 642. *Promulgation and adoption*

7 “(a) *Procedures established pursuant to*
8 *section 641 shall only be implemented after op-*
9 *portunity for public comment. Any such proce-*
10 *dures shall be consistent with the prompt com-*
11 *pletion of rulemaking proceedings.*

12 “(b)(1) *If procedures established pursuant*
13 *to section 641 include review of any initial or*
14 *final analyses of a rule required under chap-*
15 *ter 6, the time for any such review of any ini-*
16 *tial analysis shall not exceed 30 days following*
17 *the receipt of the analysis by the Director, a*
18 *designee of the President, or by an officer to*
19 *whom the authority granted under section 641*
20 *has been delegated pursuant to section 643.*

21 “(2) *The time for review of any final analy-*
22 *sis required under chapter 6 shall not exceed*
23 *30 days following the receipt of the analysis by*
24 *the Director, a designee of the President, or*
25 *such officer.*

1 ***“(3)(A) The times for each such review may***
2 ***be extended for good cause by the President or***
3 ***such officer for an additional 30 days.***

4 ***“(B) Notice of any such extension, together***
5 ***with a succinct statement of the reasons there-***
6 ***for, shall be inserted in the rulemaking file.***

7 ***“§ 643. Delegation of authority***

8 ***“(a) The President may delegate the au-***
9 ***thority granted by this subchapter to the Vice***
10 ***President or to an officer within the Executive***
11 ***Office of the President whose appointment has***
12 ***been subject to the advice and consent of the***
13 ***Senate.***

14 ***“(b)(1) Notice of any delegation, or any rev-***
15 ***ocation or modification thereof shall be pub-***
16 ***lished in the Federal Register.***

17 ***“(2) Any notice with respect to a delegation***
18 ***to the Vice President shall contain a statement***
19 ***by the Vice President that the Vice President***
20 ***will make every reasonable effort to respond to***
21 ***congressional inquiries concerning the exer-***
22 ***cise of the authority delegated under this sec-***
23 ***tion.***

1 ***“§ 644. Judicial review***

2 ***“The exercise of the authority granted***
 3 ***under this subchapter by the Director, the***
 4 ***President, or by an officer to whom such au-***
 5 ***thority has been delegated under section 643***
 6 ***shall not be subject to judicial review in any***
 7 ***manner under this chapter.”.***

8 ***(b) REGULATORY FLEXIBILITY ANALYSIS.—***

9 ***(1) JUDICIAL REVIEW.—Section 611 of***
 10 ***title 5, United States Code, is amended to***
 11 ***read as follows:***

12 ***“§ 611. Judicial review***

13 ***“(a)(1) Except as provided in paragraph***
 14 ***(2), not later than 2 years after the effective***
 15 ***date of a final rule with respect to which an***
 16 ***agency—***

17 ***“(A) certified, pursuant to section***
 18 ***605(b), that such rule would not have a***
 19 ***significant economic impact on a substan-***
 20 ***tial number of small entities;***

21 ***“(B) prepared a final regulatory flexi-***
 22 ***bility analysis pursuant to section 604; or***

23 ***“(C) did not prepare an initial regu-***
 24 ***latory flexibility analysis pursuant to sec-***
 25 ***tion 603 or a final regulatory flexibility***

1 ***analysis pursuant to section 604 except as***
2 ***permitted by sections 605 and 608,***
3 ***an affected small entity may petition for the***
4 ***judicial review of such certification, analysis,***
5 ***or lack of analysis, in accordance with this***
6 ***subsection. A court having jurisdiction to re-***
7 ***view such rule for compliance with section 553***
8 ***or under any other provision of law shall have***
9 ***jurisdiction to review such certification or***
10 ***analysis.***

11 ***“(2)(A) Notwithstanding any other provi-***
12 ***sion of law, an affected small entity shall have***
13 ***2 years to challenge such certification, analy-***
14 ***sis or lack of analysis.***

15 ***“(B) If an agency delays the issuance of a***
16 ***final regulatory flexibility analysis pursuant***
17 ***to section 608(b), a petition for judicial review***
18 ***under this subsection shall be filed not later***
19 ***than 2 years after the date the analysis is***
20 ***made available to the public.***

21 ***“(3) For purposes of this subsection, the***
22 ***term ‘affected small entity’ means a small en-***
23 ***tity that is or will be adversely affected by the***
24 ***final rule.***

1 ***“(4) Nothing in this subsection shall be***
2 ***construed to affect the authority of any court***
3 ***to stay the effective date of any rule or provi-***
4 ***sion thereof under any other provision of law.***

5 ***“(5)(A) Notwithstanding section 605, if the***
6 ***court determines, on the basis of the rule-***
7 ***making record, that there is substantial evi-***
8 ***dence to conclude that the rule would have a***
9 ***significant economic impact on a substantial***
10 ***number of small entities, the court shall order***
11 ***the agency to prepare a final regulatory flexi-***
12 ***bility analysis pursuant to section 604.***

13 ***“(B) If the agency prepared a final regu-***
14 ***latory flexibility analysis, the court may order***
15 ***the agency to take corrective action consistent***
16 ***with section 604 if the court determines, on the***
17 ***basis of the rulemaking record, that the final***
18 ***regulatory flexibility analysis was prepared by***
19 ***the agency without complying with section 604.***

20 ***“(6) The court may stay the rule or grant***
21 ***such other relief as it deems appropriate if, by***
22 ***the end of the 90-day period beginning on the***
23 ***date of the order of the court pursuant to para-***
24 ***graph (5) (or such longer period as the court***

1 *may provide), the agency fails, as appro-*
2 *priate—*

3 *“(A) to prepare the analysis required*
4 *by section 604; or*

5 *“(B) to take corrective action consist-*
6 *ent with section 604.*

7 *“(7) In making any determination or*
8 *granting any relief authorized by this sub-*
9 *section, the court shall take due account of the*
10 *rule of prejudicial error.*

11 *“(b) In an action for the judicial review of*
12 *a rule, any regulatory flexibility analysis for*
13 *such rule (including an analysis prepared or*
14 *corrected pursuant to subsection (a)(5)) shall*
15 *constitute part of the whole record of agency*
16 *action in connection with such review.*

17 *“(c) Nothing in this section bars judicial*
18 *review of any other impact statement or simi-*
19 *lar analysis required by any other law if judi-*
20 *cial review of such statement or analysis is*
21 *otherwise provided by law.”.*

22 *(2) EFFECTIVE DATE.— The amendment*
23 *made by paragraph (1) shall take effect*
24 *on the date of enactment of this Act, ex-*
25 *cept that the judicial review authorized*

1 *by section 611(a) of title 5, United States*
 2 *Code (as added by subsection (a)), shall*
 3 *apply only to final agency rules issued*
 4 *after the date of enactment of this Act.*

5 ***(c) PRESIDENTIAL AUTHORITY.—Nothing in***
 6 ***this Act shall limit the exercise by the Presi-***
 7 ***dent of the authority and responsibility that***
 8 ***the President otherwise possesses under the***
 9 ***Constitution and other laws of the United***
 10 ***States with respect to regulatory policies, pro-***
 11 ***cedures, and programs of departments, agen-***
 12 ***cies, and offices.***

13 ***(d) TECHNICAL AND CONFORMING AMEND-***
 14 ***MENTS.—***

15 ***(1) CHAPTER ANALYSIS.—Part I of title***
 16 ***5, United States Code, is amended by***
 17 ***striking out the chapter heading and***
 18 ***table of sections for chapter 6 and insert-***
 19 ***ing in lieu thereof the following:***

20 ***“CHAPTER 6—THE ANALYSIS OF***
 21 ***REGULATORY FUNCTIONS***

“SUBCHAPTER I—REGULATORY ANALYSIS

“Sec.

“601. Definitions.

“602. Regulatory agenda.

“603. Initial regulatory flexibility analysis.

“604. Final regulatory flexibility analysis.

“605. Avoidance of duplicative or unnecessary analyses.

“606. Effect on other law.

- “607. Preparation of analysis.***
- “608. Procedure for waiver or delay of completion.***
- “609. Procedures for gathering comments.***
- “610. Periodic review of rules.***
- “611. Judicial review.***
- “612. Reports and intervention rights.***

“SUBCHAPTER II—ANALYSIS OF AGENCY RULES

- “621. Definitions.***
- “622. Rulemaking cost-benefit analysis.***
- “623. Petition for cost-benefit analysis.***
- “624. Decisional criteria.***
- “625. Judicial review.***
- “626. Deadlines for rulemaking.***
- “627. Agency review of rules.***
- “628. Special rule.***

“SUBCHAPTER III—RISK ASSESSMENTS

- “631. Definitions.***
- “632. Applicability.***
- “633. Principles for risk assessment.***
- “634. Principles for risk characterization and communication.***
- “635. Requirement to prepare risk assessment.***
- “636. Requirements for assessments.***
- “637. Regulations; plan for assessing new information.***
- “638. Rule of construction.***
- “639. Regulatory priorities.***
- “640. Establishment of program.***

“SUBCHAPTER IV—EXECUTIVE OVERSIGHT

- “641. Procedures.***
- “642. Promulgation and adoption.***
- “643. Delegation of authority.***
- “644. Judicial review.”.***

1 ***(2) SUBCHAPTER HEADING.—Chapter 6***
 2 ***of title 5, United States Code, is amended***
 3 ***by inserting immediately before section***
 4 ***601, the following subchapter heading:***

1 **“SUBCHAPTER I—REGULATORY**
2 **ANALYSIS”.**

3 **SEC. 5. JUDICIAL REVIEW.**

4 **(a) SCOPE OF REVIEW.—Section 706 of title**
5 **5, United States Code, is amended to read as**
6 **follows:**

7 **“§ 706. Scope of review**

8 **“(a) To the extent necessary to reach a de-**
9 **cision and when presented, the reviewing**
10 **court shall decide all relevant questions of**
11 **law, interpret constitutional and statutory**
12 **provisions, and determine the meaning or ap-**
13 **plicability of the terms of an agency action.**
14 **The reviewing court shall—**

15 **“(1) compel agency action unlawfully**
16 **withheld or unreasonably delayed; and**

17 **“(2) hold unlawful and set aside agen-**
18 **cy action, findings and conclusions found**
19 **to be—**

20 **“(A) arbitrary, capricious, an**
21 **abuse of discretion, or otherwise not**
22 **in accordance with law;**

23 **“(B) contrary to constitutional**
24 **right, power, privilege, or immunity;**

1 ***“(C) in excess of statutory jurisdic-***
2 ***tion, authority, or limitations, or short***
3 ***of statutory right;***

4 ***“(D) without observance of proce-***
5 ***dure required by law;***

6 ***“(E) unsupported by substantial***
7 ***evidence in a proceeding subject to***
8 ***sections 556 and 557 or otherwise re-***
9 ***viewed on the record of an agency***
10 ***hearing provided by statute;***

11 ***“(F) without substantial support***
12 ***in the rulemaking file, viewed as a***
13 ***whole, for the asserted or necessary***
14 ***factual basis, as distinguished from***
15 ***the policy or legal basis, of a rule***
16 ***adopted in a proceeding subject to sec-***
17 ***tion 553; or***

18 ***“(G) unwarranted by the facts to***
19 ***the extent that the facts are subject to***
20 ***trial de novo by the reviewing court.***

21 ***“(b) In making the foregoing determina-***
22 ***tions, the court shall review the whole record***
23 ***or those parts of it cited by a party, and due***
24 ***account shall be taken of the rule of preju-***
25 ***dicial error.***

1 ***“(c) In reviewing an agency interpretation***
2 ***of a statute governing the authority for an***
3 ***agency action, including agency action taken***
4 ***pursuant to a statute that provides for review***
5 ***of final agency action, the reviewing court***
6 ***shall—***

7 ***“(1) hold erroneous and unlawful—***

8 ***“(A) an agency interpretation that***
9 ***is other than the interpretation of the***
10 ***statute clearly intended by Congress;***
11 ***or***

12 ***“(B) an agency interpretation that***
13 ***is outside the range of permissible in-***
14 ***terpretations of the statute; and***

15 ***“(2) hold arbitrary, capricious, or an***
16 ***abuse of discretion—***

17 ***“(A) an agency action as to which***
18 ***the agency—***

19 ***“(i) has improperly classified***
20 ***an interpretation as being within***
21 ***or outside the range of permissible***
22 ***interpretations; or***

23 ***“(ii) has not explained in a***
24 ***reasoned analysis why it selected***
25 ***the interpretation and why it re-***

1 ***jected other permissible interpre-***
 2 ***tations of the statute; or***

3 ***“(B) in the case of agency action***
 4 ***subject to chapter 6, an interpretation***
 5 ***that does not give the agency the***
 6 ***broadest discretion to develop rules***
 7 ***that will satisfy the decisional cri-***
 8 ***teria of section 624.***

9 ***“(d) Notwithstanding any other provision***
 10 ***of law, the provisions of this subsection shall***
 11 ***apply to, and supplement, the requirements***
 12 ***contained in any statute for the review of final***
 13 ***agency action which is not otherwise subject to***
 14 ***this subsection.”.***

15 ***(b) COURT OF FEDERAL CLAIMS.—***

16 ***(1) IN GENERAL.—Section 1491(a) of***
 17 ***title 28, United States Code, is amended—***

18 ***(A) in paragraph (1), by amending***
 19 ***the first sentence to read as follows:***
 20 ***“The United States Court of Federal***
 21 ***Claims shall have jurisdiction to***
 22 ***render judgment upon any claim***
 23 ***against the United States for mone-***
 24 ***tary relief founded either upon the***
 25 ***Constitution or any Act of Congress or***

1 ***any regulation or action of an agency,***
2 ***or upon any expressed or implied con-***
3 ***tract with the United States, in cases***
4 ***not sounding in tort, or for invalida-***
5 ***tion of any Act of Congress or any reg-***
6 ***ulation of an executive department***
7 ***that adversely affects private property***
8 ***rights in violation of the fifth amend-***
9 ***ment of the United States Constitu-***
10 ***tion.”;***

11 ***(B) in paragraph (2), by inserting***
12 ***before the first sentence the following:***
13 ***“In any case within its jurisdiction,***
14 ***the Court of Federal Claims shall***
15 ***have the power to grant injunctive***
16 ***and declaratory relief when appro-***
17 ***priate.”; and***

18 ***(C) by adding at the end the fol-***
19 ***lowing new paragraphs:***

20 ***“(4) In cases otherwise within its jurisdic-***
21 ***tion, the Court of Federal Claims shall also***
22 ***have ancillary jurisdiction, concurrent with***
23 ***the courts designated in section 1346(b), to***
24 ***render judgment upon any related tort claim***
25 ***authorized under section 2674.***

1 ***“(5) In proceedings within the jurisdiction***
 2 ***of the Court of Federal Claims which con-***
 3 ***stitute judicial review of agency action (rather***
 4 ***than de novo proceedings), the provisions of***
 5 ***section 706 of title 5 shall apply.”.***

6 ***(2) PENDENCY OF CLAIMS IN OTHER***
 7 ***COURTS.—Section 1500 of title 28, United***
 8 ***States Code, is repealed.***

9 ***(c) JUDICIAL PROCEEDINGS.—***

10 ***(1) CONSENT DECREES.—Chapter 7 of***
 11 ***title 5, United States Code, is amended by***
 12 ***adding at the end the following new sec-***
 13 ***tion:***

14 ***“§ 707. Consent decrees***

15 ***“In interpreting any consent decree in ef-***
 16 ***fect on or after the date of enactment of this***
 17 ***section that imposes on an agency an obliga-***
 18 ***tion to initiate, continue, or complete rule-***
 19 ***making proceedings, the court shall not en-***
 20 ***force the decree in a way that divests the agen-***
 21 ***cy of discretion granted to it by the Congress***
 22 ***or the Constitution to respond to changing cir-***
 23 ***cumstances, make policy or managerial***
 24 ***choices, or protect the rights of third parties.”.***

1 **(2) AFFIRMATIVE DEFENSE.—Chapter 7**
2 **of title 5, United States Code, is further**
3 **amended by adding at the end the follow-**
4 **ing new section:**

5 **“§ 708. Affirmative defense**

6 **“Notwithstanding any other provision of**
7 **law, it shall be an affirmative defense in any**
8 **enforcement action brought by an agency that**
9 **the regulated person or entity is complying**
10 **with a rule, regulation, adjudication, direc-**
11 **tive, or order of such agency or any other agen-**
12 **cy that is inconsistent, incompatible, con-**
13 **tradictory, or otherwise cannot be reconciled**
14 **with the agency rule, regulation, adjudication,**
15 **directive, or order being enforced.”.**

16 **(3) AGENCY INTERPRETATIONS IN CIVIL**
17 **AND CRIMINAL ACTIONS.—**

18 **(A) IN GENERAL.—Chapter 7 of title**
19 **5, United States Code, is further**
20 **amended by adding at the end the fol-**
21 **lowing new section:**

22 **“§ 709. Agency interpretations in civil and criminal**
23 **actions**

24 **“(a)(1) No civil or criminal penalty shall**
25 **be imposed in any action brought in a Federal**

1 *court, including an action pending on the date*
2 *of enactment of this section, for the alleged*
3 *violation of a rule, if the defendant, prior to*
4 *the alleged violation—*

5 “(A) *reasonably determined, based*
6 *upon a description, explanation, or inter-*
7 *pretation of the rule contained in the*
8 *rule’s statement of basis and purpose,*
9 *that the defendant was in compliance*
10 *with, exempt from, or otherwise not sub-*
11 *ject to, the requirements of the rule; or*

12 “(B) *was informed by the agency that*
13 *promulgated the rule, or by a State au-*
14 *thority to which had been delegated the*
15 *responsibility for ensuring compliance*
16 *with the rule, that the defendant was in*
17 *compliance with, exempt from, or other-*
18 *wise not subject to, the requirements of*
19 *the rule.*

20 “(2) *In determining, for purposes of para-*
21 *graph (1)(A), whether a defendant reasonably*
22 *relied upon a description, explanation, or in-*
23 *terpretation of the rule contained in the rule’s*
24 *statement of basis and purpose, the court shall*
25 *not give deference to any subsequent agency*

1 *description, explanation, or interpretation of*
2 *the rule relied on by the agency in the action*
3 *that had not been published in the Federal*
4 *Register or otherwise directly and specifically*
5 *communicated to the defendant by the agency,*
6 *or by a State authority to which had been dele-*
7 *gated the responsibility for ensuring compli-*
8 *ance with the rule, prior to the alleged viola-*
9 *tion.*

10 “(b)(1) *In a civil or criminal action in Fed-*
11 *eral court to redress an alleged violation of a*
12 *rule, including an action pending on the date*
13 *of enactment of this section, if the court deter-*
14 *mines that the rule in question is ambiguous,*
15 *the court shall not give deference to an agency*
16 *interpretation of the rule if the defendant re-*
17 *lied upon an interpretation of the rule to the*
18 *effect that the defendant was in compliance*
19 *with or was exempt or otherwise not subject to*
20 *the requirement of the rule, and the court de-*
21 *termines that such determination is reason-*
22 *able.*

23 “(2) *Without regard to whether the defend-*
24 *ant relied upon an interpretation that the*
25 *court determines is reasonable under para-*

1 *graph (1), if the court determines that the rule*
2 *failed to give the defendant fair warning of*
3 *the conduct that the rule prohibits or requires,*
4 *no civil or criminal penalty shall be imposed.*

5 *“(c)(1) No agency action shall be taken, or*
6 *any action or other proceeding maintained,*
7 *seeking the retroactive application of a re-*
8 *quirement against any person that is based*
9 *upon—*

10 *“(A) an interpretation of a statute,*
11 *rule, guidance, agency statement of policy,*
12 *or license requirement or condition; or*

13 *“(B) a determination of fact,*
14 *if such interpretation or determination is dif-*
15 *ferent from a prior interpretation or deter-*
16 *mination by the agency or by a State or local*
17 *government exercising authority delegated or*
18 *approved by the agency, and if such person re-*
19 *lied upon the prior interpretation or deter-*
20 *mination.*

21 *“(2) This subsection shall take effect on the*
22 *date of enactment of the Comprehensive Regu-*
23 *latory Reform Act of 1995 and shall apply to*
24 *any matter for which a final unappealable ju-*
25 *dicial order has not been issued.*

1 ***“(d) This section shall apply to the review***
2 ***by a Federal court of any order of an agency***
3 ***assessing civil administrative penalties.”.***

4 ***(B) UNPUBLISHED AGENCY GUID-***
5 ***ANCE.—Section 552(a)(1) of title 5,***
6 ***United States Code, is amended by in-***
7 ***serting at the end the following new***
8 ***sentence: “In an action brought in a***
9 ***Federal court seeking a civil or crimi-***
10 ***nal penalty for the alleged violation of***
11 ***a rule, including actions pending on***
12 ***the date of enactment of this sentence,***
13 ***no consideration shall be given to any***
14 ***interpretive rule, general statement of***
15 ***policy, or other agency guidance of***
16 ***general or specific applicability, re-***
17 ***lied upon by the agency in the action,***
18 ***that had not been published in the***
19 ***Federal Register or otherwise directly***
20 ***and specifically communicated to the***
21 ***defendant by the agency, or by a State***
22 ***authority to which had been delegated***
23 ***the responsibility for ensuring compli-***
24 ***ance with the rule, prior to the al-***
25 ***leged violation.”.***

1 **(4) TECHNICAL AMENDMENT.—The anal-**
 2 **ysis for chapter 7 of title 5, United States**
 3 **Code, is amended by adding at the end the**
 4 **following new items:**

“707. Consent decrees.

“708. Affirmative defense.

“709. Agency interpretations in civil and criminal actions.”.

5 **SEC. 6. CONGRESSIONAL REVIEW.**

6 **(a) IN GENERAL.—Title 5, United States**
 7 **Code, is amended by inserting immediately**
 8 **after chapter 7 the following new chapter:**

9 **“CHAPTER 8—CONGRESSIONAL REVIEW**
 10 **OF AGENCY RULEMAKING**

11 **“§ 801. Congressional review of agency rulemaking**

12 **“(a)(1) Before a rule takes effect as a final**
 13 **rule, the agency promulgating such rule shall**
 14 **submit to the Congress a report containing a**
 15 **copy of the rule, the notice of proposed rule-**
 16 **making, and the statement of basis and pur-**
 17 **pose for the rule, including a complete copy of**
 18 **any analysis required under chapter 6, and**
 19 **the proposed effective date of the rule. In the**
 20 **case of a rule that is not a major rule within**
 21 **the meaning of section 621(4), summary of the**
 22 **rulemaking proceedings shall be submitted.**

1 ***“(2) A rule relating to a report submitted***
2 ***under paragraph (1) shall take effect as a***
3 ***final rule, the latest of the following:***

4 ***“(A) The later of the date occurring 45***
5 ***days after the date on which—***

6 ***“(i) the Congress receives the re-***
7 ***port submitted under paragraph (1);***
8 ***or***

9 ***“(ii) the rule is published in the***
10 ***Federal Register.***

11 ***“(B) If the Congress passes a joint res-***
12 ***olution of disapproval described under***
13 ***subsection (g) relating to the rule, and the***
14 ***President signs a veto of such resolution,***
15 ***the earlier date—***

16 ***“(i) on which either House of Con-***
17 ***gress votes and fails to override the***
18 ***veto of the President; or***

19 ***“(ii) occurring 30 session days***
20 ***after the date on which the Congress***
21 ***received the veto and objections of the***
22 ***President.***

23 ***“(C) The date the rule would have oth-***
24 ***erwise taken effect, if not for this section***

1 *(unless a joint resolution of disapproval*
2 *under subsection (g) is approved).*

3 ***“(b) A rule shall not take effect as a final***
4 ***rule if the Congress passes a joint resolution***
5 ***of disapproval described under subsection (g),***
6 ***which is signed by the President or is vetoed***
7 ***and overridden by the Congress.***

8 ***“(c)(1) Notwithstanding any other provi-***
9 ***sion of this section (except subject to para-***
10 ***graph (3)), a rule that would not take effect by***
11 ***reason of this section may take effect if the***
12 ***President makes a determination under para-***
13 ***graph (2) and submits written notice of such***
14 ***determination to the Congress.***

15 ***“(2) Paragraph (1) applies to a determina-***
16 ***tion made by the President by Executive order***
17 ***that the rule should take effect because such***
18 ***rule is—***

19 ***“(A) necessary because of an imminent***
20 ***threat to health or safety or other emer-***
21 ***gency;***

22 ***“(B) necessary for the enforcement of***
23 ***criminal laws; or***

24 ***“(C) necessary for national security.***

1 ***“(3) An exercise by the President of the au-***
2 ***thority under this subsection shall have no ef-***
3 ***fect on the procedures under subsection (g) or***
4 ***the effect of a joint resolution of disapproval***
5 ***under this section.***

6 ***“(4) This subsection and an Executive***
7 ***order issued by the President under para-***
8 ***graph (2) shall not be subject to judicial re-***
9 ***view by a court of the United States.***

10 ***“(d)(1) Subsection (g) shall apply to any***
11 ***rule that is published in the Federal Register***
12 ***(as a rule that shall take effect as a final rule)***
13 ***during the period beginning on the date occur-***
14 ***ring 60 days before the date the Congress ad-***
15 ***journs sine die through the date on which the***
16 ***succeeding Congress first convenes.***

17 ***“(2) For purposes of subsection (g), a rule***
18 ***described under paragraph (1) shall be treat-***
19 ***ed as though such rule were published in the***
20 ***Federal Register (as a rule that shall take ef-***
21 ***fect as a final rule) on the date the succeeding***
22 ***Congress first convenes.***

23 ***“(3) During the period between the date***
24 ***the Congress adjourns sine die through the***
25 ***date on which the succeeding Congress first***

1 *convenes, a rule described under paragraph*
 2 *(1) shall take effect as a final rule as otherwise*
 3 *provided by law.*

4 *“(e) Any rule that takes effect and later is*
 5 *made of no force or effect by the enactment of*
 6 *a joint resolution under subsection (g) shall be*
 7 *treated as though such rule had never taken*
 8 *effect.*

9 *“(f) If the Congress does not enact a joint*
 10 *resolution of disapproval under subsection (g),*
 11 *no court or agency may infer any intent of the*
 12 *Congress from any action or inaction of the*
 13 *Congress with regard to such rule, related*
 14 *statute, or joint resolution of disapproval.*

15 *“(g)(1) For purposes of this subsection, the*
 16 *term ‘joint resolution’ means only a joint reso-*
 17 *lution introduced after the date on which the*
 18 *report referred to in subsection (a) is received*
 19 *by Congress the matter after the resolving*
 20 *clause of which is as follows: ‘That Congress*
 21 *disapproves the rule submitted by the*
 22 *_____ relating to _____, and*
 23 *such rule shall have no force or effect.’ (The*
 24 *blank spaces being appropriately filled in.)*

1 ***“(2)(A) A resolution described in para-***
2 ***graph (1) shall be referred to the committees***
3 ***in each House of Congress with jurisdiction.***
4 ***Such a resolution shall not be reported before***
5 ***the eighth day after its submission or publica-***
6 ***tion date.***

7 ***“(B) For purposes of this subsection the***
8 ***term ‘submission or publication date’ means***
9 ***the later of the date on which—***

10 ***“(i) the Congress receives the report***
11 ***submitted under subsection (a)(1); or***

12 ***“(ii) the rule is published in the Fed-***
13 ***eral Register.***

14 ***“(3) If the committee to which a resolution***
15 ***described in paragraph (1) is referred has not***
16 ***reported such resolution (or an identical reso-***
17 ***lution) at the end of 20 calendar days after its***
18 ***submission or publication date, such commit-***
19 ***tee may be discharged by the Majority Leader***
20 ***of the Senate or the Majority Leader of the***
21 ***House of Representatives, as the case may be,***
22 ***from further consideration of such resolution***
23 ***and such resolution shall be placed on the ap-***
24 ***propriate calendar of the House involved.***

1 ***“(4)(A) When the committee to which a res-***
2 ***olution is referred has reported, or when a***
3 ***committee is discharged (under paragraph***
4 ***(3)) from further consideration of, a resolution***
5 ***described in paragraph (1), it shall at any***
6 ***time thereafter be in order (even though a pre-***
7 ***vious motion to the same effect has been dis-***
8 ***agreed to) for any Member of the respective***
9 ***House to move to proceed to the consideration***
10 ***of the resolution, and all points of order***
11 ***against the resolution (and against consider-***
12 ***ation of the resolution) shall be waived. The***
13 ***motion shall be highly privileged in the House***
14 ***of Representatives and shall be privileged in***
15 ***the Senate and shall not be debatable. The mo-***
16 ***tion shall not be subject to amendment, or to***
17 ***a motion to postpone, or to a motion to proceed***
18 ***to the consideration of other business. A mo-***
19 ***tion to reconsider the vote by which the motion***
20 ***is agreed to or disagreed to shall not be in***
21 ***order. If a motion to proceed to the consider-***
22 ***ation of the resolution is agreed to, the resolu-***
23 ***tion shall remain the unfinished business of***
24 ***the respective House until disposed of.***

1 ***“(B) Debate on the resolution, and on all***
2 ***debatable motions and appeals in connection***
3 ***therewith, shall be limited to not more than 10***
4 ***hours, which shall be divided equally between***
5 ***those favoring and those opposing the resolu-***
6 ***tion. A motion further to limit debate shall be***
7 ***in order and shall not be debatable. An***
8 ***amendment to, or a motion to postpone, or a***
9 ***motion to proceed to the consideration of other***
10 ***business, or a motion to recommit the resolu-***
11 ***tion shall not be in order. A motion to recon-***
12 ***sider the vote by which the resolution is agreed***
13 ***to or disagreed to shall not be in order.***

14 ***“(C) Immediately following the conclusion***
15 ***of the debate on a resolution described in***
16 ***paragraph (1), and a single quorum call at the***
17 ***conclusion of the debate if requested in ac-***
18 ***cordance with the rules of the appropriate***
19 ***House, the vote on final passage of the resolu-***
20 ***tion shall occur.***

21 ***“(D) Appeals from the decisions of the***
22 ***Chair relating to the application of the rules***
23 ***of the Senate or the House of Representatives,***
24 ***as the case may be, to the procedure relating***

1 *to a resolution described in paragraph (1)*
2 *shall be decided without debate.*

3 *“(5) If, before the passage by one House of*
4 *a resolution of that House described in para-*
5 *graph (1), that House receives from the other*
6 *House a resolution described in paragraph (1),*
7 *then the following procedures shall apply:*

8 *“(A) The resolution of the other House*
9 *shall not be referred to a committee.*

10 *“(B) With respect to a resolution de-*
11 *scribed in paragraph (1) of the House re-*
12 *ceiving the resolution—*

13 *“(i) the procedure in that House*
14 *shall be the same as if no resolution*
15 *had been received from the other*
16 *House; but*

17 *“(ii) the vote on final passage*
18 *shall be on the resolution of the other*
19 *House.*

20 *“(6) This subsection is enacted by Con-*
21 *gress—*

22 *“(A) as an exercise of the rulemaking*
23 *power of the Senate and House of Rep-*
24 *resentatives, respectively, and as such it is*
25 *deemed to be a part of the rules of each*

1 *House, respectively, but applicable only*
 2 *with respect to the procedure to be fol-*
 3 *lowed in that House in the case of a reso-*
 4 *lution described in paragraph (1), and it*
 5 *supersedes other rules only to the extent*
 6 *that it is inconsistent with such rules; and*

7 *“(B) with full recognition of the con-*
 8 *stitutional right of either House to change*
 9 *the rules (so far as relating to the proce-*
 10 *dure of that House) at any time, in the*
 11 *same manner, and to the same extent as*
 12 *in the case of any other rule of that*
 13 *House.*

14 *“(h) This section shall not apply to rules*
 15 *that concern monetary policy proposed or im-*
 16 *plemented by the Board of Governors of the*
 17 *Federal Reserve System or the Federal Open*
 18 *Market Committee.”.*

19 *(b) TECHNICAL AMENDMENT.—The table of*
 20 *chapters for part I of title 5, United States*
 21 *Code, is amended by inserting immediately*
 22 *after the item relating to chapter 7 the follow-*
 23 *ing:*

“8. Congressional Review of Agency Rulemaking 801”.

1 **SEC. 7. ACCOUNTING.**

2 **(a) DEFINITIONS.—For purposes of this sec-**
3 **tion, the following definitions apply:**

4 **(1) REGULATION.—The term “regula-**
5 **tion” means an agency statement of gen-**
6 **eral applicability and future effect de-**
7 **signed to implement, interpret, or pre-**
8 **scribe law or policy or describing the pro-**
9 **cedures or practice requirements of an**
10 **agency. The term shall not include—**

11 **(A) administrative actions gov-**
12 **erned by sections 556 and 557 of title**
13 **5, United States Code;**

14 **(B) regulations issued with respect**
15 **to a military or foreign affairs func-**
16 **tion of the United States; or**

17 **(C) regulations related to agency**
18 **organization, management, or person-**
19 **nel.**

20 **(2) AGENCY.—The term “agency”**
21 **means any executive department, military**
22 **department, Government corporation,**
23 **Government controlled corporation, or**
24 **other establishment in the executive**
25 **branch of the Government (including the**
26 **Executive Office of the President), or any**

1 ***independent regulatory agency, but shall***
2 ***not include—***

3 ***(A) the General Accounting Office;***

4 ***(B) the Federal Election Commis-***
5 ***sion;***

6 ***(C) the governments of the District***
7 ***of Columbia and of the territories and***
8 ***possessions of the United States, and***
9 ***their various subdivisions; or***

10 ***(D) Government-owned contractor-***
11 ***operated facilities, including labora-***
12 ***tories engaged in national defense re-***
13 ***search and production activities.***

14 ***(b) ACCOUNTING STATEMENT.—***

15 ***(1) IN GENERAL.—(A) The President***
16 ***shall be responsible for implementing and***
17 ***administering the requirements of this***
18 ***section.***

19 ***(B) Every 2 years, not later than June***
20 ***of the second year, the President shall***
21 ***prepare and submit to Congress an ac-***
22 ***counting statement that estimates the***
23 ***costs of Federal regulatory programs and***
24 ***corresponding benefits in accordance***
25 ***with this subsection.***

1 **(2) YEARS COVERED BY ACCOUNTING**
2 **STATEMENT.—Each accounting statement**
3 **shall cover, at a minimum, the 5 fiscal**
4 **years beginning on October 1 of the year**
5 **in which the report is submitted and may**
6 **cover any fiscal year preceding such fiscal**
7 **years for purpose of revising previous esti-**
8 **mates.**

9 **(3) TIMING AND PROCEDURES.—(A) The**
10 **President shall provide notice and oppor-**
11 **tunity for comment for each accounting**
12 **statement. The President may delegate to**
13 **an agency the requirement to provide no-**
14 **tice and opportunity to comment for the**
15 **portion of the accounting statement relat-**
16 **ing to that agency.**

17 **(B) The President shall propose the**
18 **first accounting statement under this sub-**
19 **section not later than 2 years after the**
20 **date of the enactment of this Act and**
21 **shall issue the first accounting statement**
22 **in final form not later than 3 years after**
23 **the date of the enactment of this Act. Such**
24 **statement shall cover, at a minimum,**

1 *each of the 8 fiscal years beginning after*
2 *the date of the enactment of this Act.*

3 **(4) CONTENT OF ACCOUNTING STATE-**
4 **MENT.—(A) Each accounting statement**
5 **shall contain estimates of costs and bene-**
6 **fits with respect to each fiscal year cov-**
7 **ered by the statement in accordance with**
8 **this paragraph. For each such fiscal year**
9 **for which estimates were made in a pre-**
10 **vious accounting statement, the statement**
11 **shall revise those estimates and state the**
12 **reasons for the revisions.**

13 **(B)(i) An accounting statement shall**
14 **estimate the costs of Federal regulatory**
15 **programs by setting forth, for each year**
16 **covered by the statement—**

17 **(I) the annual expenditure of na-**
18 **tional economic resources for the reg-**
19 **ulatory program; and**

20 **(II) such other quantitative and**
21 **qualitative measures of costs as the**
22 **President considers appropriate.**

23 **(ii) For purposes of the estimate of**
24 **costs in the accounting statement, na-**
25 **tional economic resources shall include,**

1 ***and shall be listed under, at least the fol-***
2 ***lowing categories:***

3 ***(I) Private sector costs.***

4 ***(II) Federal sector administrative***
5 ***costs.***

6 ***(III) Federal sector compliance***
7 ***costs.***

8 ***(IV) State and local government***
9 ***administrative costs.***

10 ***(V) State and local government***
11 ***compliance costs.***

12 ***(VI) Indirect costs, including op-***
13 ***portunity costs.***

14 ***(C) An accounting statement shall es-***
15 ***timate the benefits of Federal regulatory***
16 ***programs by setting forth, for each year***
17 ***covered by the statement, such quan-***
18 ***titative and qualitative measures of bene-***
19 ***fits as the President considers appro-***
20 ***priate. Any estimates of benefits concern-***
21 ***ing reduction in health, safety, or environ-***
22 ***mental risks shall present the most plau-***
23 ***sible level of risk practical, along with a***
24 ***statement of the reasonable degree of sci-***
25 ***entific certainty.***

1 ***(c) ASSOCIATED REPORT TO CONGRESS.—***

2 ***(1) IN GENERAL.—At the same time as***
3 ***the President submits an accounting***
4 ***statement under subsection (b), the Presi-***
5 ***dent, acting through the Director of the***
6 ***Office of Management and Budget, shall***
7 ***submit to Congress a report associated***
8 ***with the accounting statement (herein-***
9 ***after referred to as an “associated re-***
10 ***port”). The associated report shall con-***
11 ***tain, in accordance with this subsection—***

12 ***(A) analyses of impacts; and***

13 ***(B) recommendations for reform.***

14 ***(2) ANALYSES OF IMPACTS.—The Presi-***
15 ***dent shall include in the associated report***
16 ***the following:***

17 ***(A) Analyses prepared by the***
18 ***President of the cumulative impact of***
19 ***Federal regulatory programs covered***
20 ***in the accounting statement on the***
21 ***following:***

22 ***(i) The ability of State and***
23 ***local governments to provide es-***
24 ***sential services, including police,***
25 ***fire protection, and education.***

1 ***(ii) Small business.***

2 ***(iii) Productivity.***

3 ***(iv) Wages.***

4 ***(v) Economic growth.***

5 ***(vi) Technological innovation.***

6 ***(vii) Consumer prices for***
7 ***goods and services.***

8 ***(viii) Such other factors con-***
9 ***sidered appropriate by the Presi-***
10 ***dent.***

11 ***(B) A summary of any independent***
12 ***analyses of impacts prepared by per-***
13 ***sons commenting during the comment***
14 ***period on the accounting statement.***

15 ***(3) RECOMMENDATIONS FOR REFORM.—***
16 ***The President shall include in the associ-***
17 ***ated report the following:***

18 ***(A) A summary of recommenda-***
19 ***tions of the President for reform or***
20 ***elimination of any Federal regulatory***
21 ***program or program element that***
22 ***does not represent sound use of na-***
23 ***tional economic resources or other-***
24 ***wise is inefficient.***

1 **(B) A summary of any rec-**
2 **ommendations for such reform or**
3 **elimination of Federal regulatory pro-**
4 **grams or program elements prepared**
5 **by persons commenting during the**
6 **comment period on the accounting**
7 **statement.**

8 **(d) GUIDANCE FROM OFFICE OF MANAGEMENT**
9 **AND BUDGET.—The Director of the Office of**
10 **Management and Budget shall, in consulta-**
11 **tion with the Council of Economic Advisers,**
12 **provide guidance to agencies—**

13 **(1) to standardize measures of costs**
14 **and benefits in accounting statements**
15 **prepared pursuant to sections 3 and 7 of**
16 **this Act, including—**

17 **(A) detailed guidance on estimat-**
18 **ing the costs and benefits of major**
19 **rules; and**

20 **(B) general guidance on estimat-**
21 **ing the costs and benefits of all other**
22 **rules that do not meet the thresholds**
23 **for major rules; and**

24 **(2) to standardize the format of the**
25 **accounting statements.**

1 **(e) RECOMMENDATIONS FROM CONGRES-**
2 **SIONAL BUDGET OFFICE.—After each accounting**
3 **statement and associated report submitted to**
4 **Congress, the Director of the Congressional**
5 **Budget Office shall make recommendations to**
6 **the President—**

7 **(1) for improving accounting state-**
8 **ments prepared pursuant to this section,**
9 **including recommendations on level of de-**
10 **tail and accuracy; and**

11 **(2) for improving associated reports**
12 **prepared pursuant to this section, includ-**
13 **ing recommendations on the quality of**
14 **analysis.**

15 **SEC. 8. STUDIES AND REPORTS.**

16 **(a) RISK ASSESSMENTS.—The Administra-**
17 **tive Conference of the United States shall—**

18 **(1) develop and carry out an ongoing**
19 **study of the operation of the risk assess-**
20 **ment requirements of subchapter III of**
21 **chapter 6 of title 5, United States Code (as**
22 **added by section 4 of this Act); and**

23 **(2) submit an annual report to the**
24 **Congress on the findings of the study.**

1 ***(b) ADMINISTRATIVE PROCEDURE ACT.—Not***
 2 ***later than December 31, 1996, the Administra-***
 3 ***tive Conference of the United States shall—***

4 ***(1) carry out a study of the operation***
 5 ***of the Administrative Procedure Act (as***
 6 ***amended by section 3 of this Act); and***

7 ***(2) submit a report to the Congress on***
 8 ***the findings of the study, including pro-***
 9 ***posals for revision, if any.***

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